CCTS's Collaborative Efforts Facilitate Clinical and Translational Research

By Pamela Lewis, *Institutional Advancement*

Boundaries of many sorts are being crossed in the 9-month-old Center for Clinical and Translational Sciences (CCTS), one of 12 such centers nationwide funded in the first tier of what may eventually be 60 National Institutes of Health (NIH) Clinical and Translational Science Awards (CTSA). First of all, says Maureen Goode, Ph.D., CCTS administrative director, the local site is a collaborative effort among The University of Texas Health Science Center at Houston, where it is based, the UT M. D. Anderson Cancer Center and the Memorial Hermann Healthcare System.

The NIH designed the CTSA program to solve problems that slow down clinical and translational research, explains Dr. Goode, who came to the CCTS from the cancer center. "The purpose of the CTSA program is to speed up the research and to get findings more quickly from bench to bedside to community and back. The NIH gave us a mandate: to synergize and transform clinical and translational research in ways that cross boundaries of departments, schools, and institutions." To accomplish this, the CCTS put together a program of 12 components to provide assistance with training of new investigators; study design, conduct, and analysis; ethical, regulatory, and informatics issues; core laboratory services; pilot funding; and transfer of information to and from the community.

Even at the national level there's more collaboration among the 12 sites than Dr. Goode's ever seen before. "We're working as a consortium among these components. Most of the sites have similar components and through meetings at NIH and through video conferencing we are all working together across the country to try to figure out how to do this in the best possible way," she says.

The Houston group's various strengths are very complementary, says the administrator. "We are very lucky: M. D. Anderson has strengths in clinical trial research and translational research, specifically cancer-oriented, as well as strong education programs; the health science center has a much broader range of research, and strengths in many educational areas, as well as the Clinical Research Center operated by the UT Medical School and Memorial Hermann-TMC, which has been very active. In addition, the Memorial Hermann Hospital System brings in community health care workers from all over Houston. And the Clinical Research Unit in Brownsville serves a unique population. All these areas were very important in us being selected as one of the first CTSA sites. We have a great team."

Maureen Goode, Ph.D., left, administrative director, Center for Clinical and Translational Science, meets with Barbara Legate, senior business systems analyst in the Office of Research. *Photo by Natalie Wong Camarata*

The center's collaborative focus is essential, says Dr. Goode, because research doesn't stop once new therapies get to the clinic. "Clinical observations about why therapies are successful on some patients and not others are extremely important. They lead us to look at targeted therapies or overturn long-held ideas."

Using CCTS

The center is the place where people should come first when they are thinking about doing translational research, maybe even before they know what kinds of questions to ask, she says.

"Some people who come to us already have a lot of expertise and know exactly what kind of help they need — for example, they want advice from our regulatory group on filing an investigational new drug application for a new therapy they've developed. But other investigators need more help — for instance, a new assistant professor who has just come to Houston to start up a research program may need help formulating a testable hypothesis and finding out how to fund a study and who else is working in the same area," Dr. Goode explains.

There are many ways in which new investigators can get help from the CCTS. Hypothesis-generating meetings might first take place, in which an assistant professor says, "OK, I have this idea. I'd like to do a prospective study on this particular disease and here are my thoughts on what I want to do." Then, the CCTS administrative group gets together several people from the Engine of Innovation Think Tank with expertise in that area or on how to design studies in general, she says.

"They'll work with the principal investigator (PI), asking questions such as, 'Have you thought about the fact that it will take you five years to get enough patients to complete the study, so maybe you should do a retrospective study instead?' They can provide an enormous amount of advice for people who are just beginning."

SPARK an idea

PIs with a sound hypothesis for a clinical study can benefit from meetings with the SPARK (Scientific Partners for Research Kickoff) team, Dr. Goode explains. SPARK, which is based in the CCTS's Clinical Research Center, helps investigators start and complete their studies faster by providing initial advice, monitoring study progress and stepping in to assist when needed. To further speed up the process, the Clinical Research Center has merged its application into the institutional iRIS application, so that PIs can apply for both at once.

While departments and schools provide a certain amount of help for researchers who are just beginning, Dr. Goode says that in her experience, "It's really helpful to be able to come to some place like the CCTS and be able to ask: 'How do I start planning a clinical trial?' 'How do I find grant opportunities?' 'Where can I get control DNA samples from normal individuals?' 'Can someone help me with quantitative polymer chain reaction?' 'Are research coordinators available?'

"It breaks my heart," she says, "to see people trying to reinvent the wheel when they could get help from us instead."

In addition to consultations, the CCTS also has formal training and career development programs, including didactic programs and support for predoctoral students, medical fellows, and assistant professors. "We try to fill the gaps in people's knowledge. I think our approach is unique among the CTSA centers because it's not one size fits all. Those we educate may be the potential principal investigators of major studies; others may play a supporting role. They may not need to know as much, so we are setting up programs for people at different levels," Dr. Goode says.

Also of help to the researchers will be the Biobank, a source of biological samples and genetic marker data. "It started out as a virtual biobank — a compendium of data — but has evolved into an actual sample repository," she says.

"It's very exciting, we are extending different aspects of it to physicians in the community, which is a big push that NIH is doing. Memorial Hermann has a big part with that and the School of Public Health also has that community component," she adds.

Community engagement also is a big part of the program.

"We need to alert the public to what's happening in health research, and we need feedback from them on their health concerns. So, we're working with the greater Houston community and communities in the lower Rio Grande valley," Dr. Goode says.

"We are here to serve people and share our expertise in every aspect of clinical and translational research," Dr. Goode concludes.

For information on the Clinical Research Center, contact ms.gcrc@uth.tmc.edu, 713-704-4137; for information on SPARK, contact Sandra Williams, 713-500-7926, or Madelene Ottosen, 713-704-4147. For information on other aspects of the CCTS, contact Maureen.Goode@uth.tmc.edu, 713-704-5115. ★

Keeping the HSC Running in the Event of an Emergency

The University of Texas Health Science Center at Houston already has experienced, and may encounter again, any of a variety of emergency situations. Depending on an emergency's severity, the institution could be drastically impacted, making it problematic to fulfill its stated missions or handle daily business transactions.

To minimize both the frequency and severity of emergency situations on the institution, the health science center maintains a proactive environmental health and safety program that works to prevent the occurrence of emergency events, and to mitigate the extent of any emergencies that might arise.

In the same vein, says Robert J. Emery, Dr.P.H., assistant vice president for Safety, Health, Environment and Risk Management, the university must have contingency plans in place to deal with how we do business after such an emergency.

"Based upon the experience with Tropical Storm Allison," says Emery, "30 days post event is the most critical time frame with regard to immediate recovery decisions, resource procurement and the establishment of temporary means and locations of essential functions."

Therefore, a Business Continuity Plan has been established for the university to provide recommended actions and decision-making capabilities needed within that time frame.

Essential infrastructure services, such as communication about access to and condition of facilities, information systems availability and operational status, will be needed to pay employees, acquire and pay for goods and services, bill for services, collect and deposit proceeds and take care of needed student housing and transportation, as well as operation of the UT Professional Building and garage and the University Center Tower garage.

The Emergency Situation Response Plan (ESRP), the IT Disaster Recovery Plan, and the business continuity plan provide a comprehensive guide for operating in a period leading up to and for 30 days after an event.

Business Continuity Education

To ensure business continuity in the event of an emergency, says Emery, first we must make sure that all students, faculty and staff are educated about the importance of being prepared at home because "institutional preparations are essentially useless if the individuals who make the processes happen are preoccupied with issues at home."

- So, supervisors and instructors should encourage their employees and students to make "all hazards" preparations for home emergency situations, including care for family and pets during any type of emergency. Remember, says Emery, the health science center is not a place of refuge for family and pets in emergency situations, hence the increased need for at home preparations."
- Everyone should carry with them at all times supervisor or entity contact information so they can make notifications if they are unable to report to work or class.
- Employees who have been identified by their supervisors as critical to the continued operation of the unit are expected to have preparations in place for their families and pets so that they can fulfill their work obligations.
- Students and employees are responsible for knowing how to access information about the university's open, restricted or closed status (see information/communication, below).
- If the institution is open, but faculty, staff or students are unable to get to classes or the workplace for any reason, the appropriate supervisor must be notified and the appropriate type of leave time must be utilized.
- If the institution is in a restricted-access condition, only individuals absolutely needing access to university buildings will be allowed. Examples of such essential persons would include animal care workers and facilities support personnel.
- In situations where the institution is closed (e.g. government-mandated evacuation), no building access will be permitted.

Information/Communication

During any period governed by the ESRP, information/communications will be driven by the Executive Team, which retains the authority to suspend operations. The decision to suspend operations will be applied to all schools and departments on a consistent basis.

If operations must be suspended during normal business hours (8 a.m.-5 p.m., Monday-Friday), the Executive Team will request that designated members of the Office of Institutional Advancement's (OIA) Communications and Media Relations Teams notify all Level 4 Essential and Advisory personnel and administrative department heads.

In an emergency situation, faculty, staff and students may obtain information about the institution's official status by:

- Viewing the university's home page, http://www.uthouston.edu.
- Tuning to radio stations: KILT-AM 610, KILT-FM 100.3, KPRC-AM 950, or KTRH-AM 740. Local television stations KHOU 11, KHCW 39, KPRC 2, KRIV 26, KTRK 13, KXLN 45 and KTMD 47 are notified but may not always run the information.

In the event of severe weather:

- Most faculty, staff and students should call 713- 500-9996 to find out the health science center's operational status.
- UT Harris County Psychiatric Center employees should call 713-741-5001.
- Faculty, staff and students located at the Medical School, John Freeman Building, UT Professional Building, Cyclotron facility or Jesse Jones Library building should call 713- 500-7999.

For the 30 days following an event that compromises facilities and systems, the primary method for conveying campus information will be http://www.uthoustonemergency.org/. The Web site will provide information regarding the status of facilities, the information system and operations, using a green (fully operational), yellow (diminished capacity) or red (closure/failure) approach.

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