

## ▶ NIH Clinical Center Collaborates with CTSA

The NIH Clinical Center (CC), NIH's clinical research hospital in Bethesda, Maryland, offers unparalleled opportunities for collaborations through the Clinical and Translational Science Award (CTSA) program. About 1,500 clinical studies are currently being conducted at the CC, the world's largest clinical research complex.

"Collaboration is the foundation for the bench-to-bedside clinical research conducted here, and the CTSA program provides new possibilities for partnerships that will ultimately improve health and health care," said Dr. John I. Gallin, CC director. "Our goal is to share expertise, provide models for effective programs, and improve access to specialized resources." One such example is a collaboration between the CC and the CTSA at Rockefeller University to survey research subjects about their perceptions of the clinical trial experience. The effort is currently being expanded to include all interested CTSA.

Re-engineering the clinical research enterprise is a key objective of the NIH Roadmap for Medical Research. Several recommendations in the 2004 NIH Director's Blue Ribbon Panel focused on the CC's role in providing education in the discipline and in fostering partnerships in the extramural community. In response, the CC has developed or expanded a range of programs to support and nurture clinical research.

### CLINICAL RESEARCH TRAINING

"Investigators need a firm grounding in the increasingly complex conduct of

clinical research, and the CC developed formal coursework because the training was not widely available," said Dr. Gallin. Course topics include clinical research practice, ethics, and pharmacology. Many students take the courses from remote sites via teleconference or using lectures on DVD. Information is available online at <http://clinicalcenter.nih.gov/researchers/training.shtml>.

### COLLABORATIVE RESEARCH

To encourage collaborations among basic scientists and clinical investigators, the CC created the Bench-to-Bedside Awards to speed translation of promising laboratory discoveries into new medical treatments. Recently, this program was opened to teams including extramural partners. This pilot was such a success that a formal evaluation is under way to determine opportunities for expansion. For more information, visit <http://clinicalcenter.nih.gov/cc/btb/awards.shtml>.

### INFORMATICS

The CC's Clinical Research Information System (CRIS) facilitates clinical care while supporting the collection of clinical and research data. The system's next phase is a data mart, which will pool data, text, and images from CRIS and make them available to intramural researchers. Future plans include a repository to enable data sharing with extramural researchers.

ProtoType is a Web-based clinical protocol writing tool—available to the extramural community—that provides investigators with a standard protocol structure, online help, and templates of suggested language. Investigators use it to put ideas for new protocols into the



■ John I. Gallin, director of the NIH Clinical Center, talks with one of his patients, Amanda Young of Georgia.

proper format to satisfy regulations and facilitate review.

### SPECIALIZED RESOURCES

Innovative product development services in both pharmacy and cell processing support the NIH clinical research mission while meeting the rigorous requirements of drug, biologic, and tissue manufacturing regulations. The CC programs serve as a model for extramural researchers. Resources also include investigation-focused surgery, imaging capability, and specialized patient-care components.

All CC patients participate in a clinical research protocol and half have rare diseases. These special cohorts of patients provide unique opportunities for partnerships with the extramural community, some of which have been funded by the Office of Rare Diseases ([http://rarediseases.info.nih.gov/asp/resources/intr\\_res.asp](http://rarediseases.info.nih.gov/asp/resources/intr_res.asp)). A list of current CC studies at <http://clinicalstudies.info.nih.gov> is another information source for extramural investigators.

For more information, contact Dr. Gallin at [cc-director@cc.nih.gov](mailto:cc-director@cc.nih.gov). ■