

CTSA FACT SHEET

Highlights from the 2006 CTSA Grantees

Prepared: December 2007

(The highlights listed below are provided in part by CTSA grantees and reflect a broad range of activities in their first year of funding.)

Columbia University

Investing in Information and Communication Technology to Manage Chronic Disease

With a six-month planning grant from Columbia's CTSA Pilot and Collaborative Science Resource, a multi-disciplinary team is betting that new information and communication technology (ICT) can help patients with chronic diseases enjoy better health by giving them improved tools to manage their own illnesses. Led by Drs. Suzanne Bakken and Thomas Pickering, the group's initial focus is hypertension. ICT interventions, they believe, will cost less than current care and produce a greater reduction in blood pressure and overall cardiovascular risk. After six months of planning, this team will compete with three others for an additional \$125,000 in pilot funds that will allow this idea to move even further ahead. Working with software designers, health economists, and patients to develop and test new interventions, this multidisciplinary team believes such techniques as home blood pressure monitoring, patient-provider communication via the Internet, and motivational interviewing can get patients more involved in their own care, ultimately cost less, and produce a greater reduction in blood pressure than current care.

Centralized Training Resources Support Career Development, Encourage Collaboration

Columbia University's Research Education, Training, and Career Development Resource, or TRANSFORM program, offers centralized training resources for cross-campus individuals who have received certain NIH career development awards (K recipients). The program is co-led

by Drs. Melissa Begg, Karina Davidson, and Robert Winchester. "We realized that all K awardees need exposure to successful R01 grants as well as a structured approach to writing, and then receiving reviews on, their first R01 submission" says Davidson. "We have started the process to identify the training needs of our K recipients, and we will structure and support the writing of their first R01 application." Aiding physician, public health, nursing, and dental K trainees to take the next step toward research independence exemplifies the kind of CTSA innovative training program needed to advance clinical and translational research. "By bringing diverse scientists together at the beginning of their scientific career, we believe we can forge new collaborations and multidisciplinary teams to tackle the large, complex public health challenges we face," says Davidson.

National Network Connects Patients with Researchers in Effort to Reduce Health Disparities

In an effort to reduce health disparities among urban and often minority communities nationwide as well as provide improved access to clinical trials and their results, NIH began a fact-finding mission aimed at improving access to its research by establishing networks of qualified community-based clinicians/investigators. Called the National Clinical Research Associates (NCRA), the clinicians of this network are trained to initiate research studies efficiently and can provide community access to studies and their results. Columbia University's CTSA received one of four contracts (along with Duke, Mayo, and Rochester) awarded for this purpose.

The contract supports formative data collection to determine the interest and capability for community-based research in four types of community medical practices: 1) suburban private medical practice, 2) urban private medical practice, 3) large multisite group practice affiliated with New York-Presbyterian Hospital, and 4) the Columbia Advanced Practice Nurse Associates ambulatory care practice.

The grant will enable this team to meet with community leaders, clinicians, and patients to determine the interest in clinical research and gather perceptions about the resources needed. The effort, a nationwide network of research support organizations, centrally coordinated by NIH, could dramatically shorten the time from laboratory innovation to best clinical practices, thus accelerating advances in human health and decreasing the cost of delivering medical research innovation into the mainstream of health care.

Web Site: <http://irvinginstitute.columbia.edu>

Duke University

Intra-Institute Collaborations Speed Research Progress

Scientists at the Duke Translational Research Institute (DTRI) are collaborating and building upon one another's research advances to accelerate research progress. An example of this lies within the DTRI's Surgical Oncology Research Facility, where Dr. Kent Weinhold, director of the DTRI's Immune Monitoring and Vaccines Core, and his colleagues translate emerging research on human immune function into exquisitely sensitive and standardized assays.

By measuring biochemical changes detectable in biological specimens with assay technologies, such as multiparameter flow cytometry, ELISA, ELISpot, and multiplex bead arrays, the Immune Monitoring core lab can detect and quantify subtle changes in markers of immune function and elucidate processes involved in immune response. In diseases where these processes are disturbed or need to be manipulated therapeutically, data pointing to subtle alterations of function but not detectable by standard, broadly available laboratory methods can provide critical insight.

“What we are providing through this core lab is access to sophisticated, comprehensive, state-of-the-art immunologic testing beyond that routinely available to Duke translational scientists,” offers Weinhold. “In many instances, this is a critical need as promising new strategies move into clinical testing.”

Partnering with the Immune Monitoring core lab at the right moment in a project's evolution could save researchers months of work, strengthen grant applications and manuscripts, and generate reproducible data with esoteric assays that are difficult to develop and nearly impossible to validate independently.

Connecting Researchers with Valuable Research Tools

The Duke Translational Research Institute is opening doors for researchers by providing them with access to invaluable research tools. An example of one of these powerful tools is a new searchable image repository system. Known as “SQUID,” the Scalable Query Utility & Image Database provides an easy way for investigators to manage a variety of imagery used in their research. SQUID can receive image data, such as magnetic resonance imaging and positron emission tomography images, directly from scanners into the system, providing Duke university and medicine researchers access to a robust storehouse of digital images. SQUID has evolved into a cost-effective tool for compliant storage, viewing, back-up, and analysis of study images. Other research tools offered by the Image Core include boilerplate language for grant applications and budget justifications, language describing the technology for institutional review board submissions, regulatory applications and study materials, and consulting from study design to interpretation of imaging data.

Web Site: www.dtmi.duke.edu

Mayo Clinic

Conducting Research Through a Mobile Clinical Research Unit

Through the Mayo Clinic Center for Translational Science Activities, new opportunities for conducting research are being explored. Research protocols that were formerly impossible within a traditional setting are now possible. A Mobile Clinical Research Unit brings resources and highly trained staff of two existing Mayo clinical research unit sites to the bedsides of acutely ill patients, into operating and emergency rooms, and out into the community. Past experience has shown that asking staff nurses to add research duties is not practical; without specialized training, it is difficult for them to properly execute the research protocols, and of course, their first priority must be to attend to the medical needs of patients. This mobile facility sends trained research RNs and technicians to collect and transport specimens, administer study drugs, and gather data according to protocol guidelines, allowing the regular staff nurses to concentrate on their assigned patient care duties. Six full-time staff members (RNs and research technicians) were added to the clinical research units to accommodate increased demand. Full 24-hour coverage is anticipated within the next six to nine months. There are currently 24 active protocols being conducted outside the traditional clinical research unit setting, and the mobile unit staff conducted specimen collection at Winona State University for a genotyping study in March 2008.

For more information about the Mayo Clinic Center for Translational Science Activities clinical research unit and Translational Technology Cores, visit: http://ctsa.mayo.edu/research_resources.

Inspiring Tomorrow's Researchers: Partnership with the University of Puerto Rico

The Mayo Clinic CTSA Education Resources and the Office of Diversity in Clinical Research are offering a two-week clinical research practicum for selected audiences at the University of Puerto Rico (UPR)–Medical Sciences Campus in collaboration with the UPR School of Medicine Endowed Health Services Research Center. The intense learning experience provides the opportunity for UPR students to come to the Mayo Clinic in Rochester, Minn., to observe clinical research in action, explore areas of research interest, and meet potential faculty mentors.

Hispanics are a fast-growing population segment in the Midwest region—and across much of the country. In planning for future needs, the Mayo Clinic has identified an urgent need to increase the number of Hispanic physicians and investigators to serve this growing community. Research indicates that culturally matched providers are much more effective both in delivering care and encouraging research participation.

The Clinical Research in Action practicum is a carefully planned program of professional development targeted for residents, fellows, and junior faculty (minority physicians) in an effort to improve research at minority institutions and partnerships with Mayo investigators. Mayo researchers are hopeful that exposing UPR students to the people and resources of Mayo Clinic early in their careers will lead not only to increased enrollment in its postdoctoral research education programs but also to more and stronger research collaborations that will benefit populations in both Puerto Rico and the Midwest.

Web Site: <http://ctsa.mayo.edu>

Oregon Health & Science University

Collaborating on Prenatal Development

Dr. Daniel Marks, a physician-scientist at Oregon Health & Science University, received a pilot grant through the university's CTSA to work on a project to study the effects of a diet high in fat and calories on prenatal development in a nonhuman primate. The pilot grant was invaluable to Marks, because he did not have a record of published research in this area. In addition, the CTSA provided training opportunities for a graduate student and a medical student in Marks' laboratory.

After supporting Marks' research using an animal model of overnutrition, the university's CTSA is helping him to take

the work to the next level by examining its potential implications for human health. Marks had documented an accumulation of fat in the livers of Japanese macaque fetuses whose mothers were fed a diet of 35 percent fat, the proportion of fat in the average U.S. diet. The accumulation of fat in the fetal livers was associated with inflammation and scarring, a picture reminiscent of the liver disease typically observed in alcoholics. To examine whether the same types of problems would occur in human fetuses, Marks started collaborating with physicians at the neonatal intensive care unit of the university's affiliated children's hospital to examine the livers of human fetuses by ultrasound.

To carry out this important study, he is receiving assistance from his institution's CTSA in fulfilling the necessary regulatory requirements, including developing consent forms and drafting operating procedures, such as how the data will be managed and how patient privacy will be protected.

A Unique Partnership: Using Technology to Better Detect and Treat Common Diseases

Researchers at the Oregon Clinical and Translational Research Institute (OCTRI) are partnering with Intel to explore and fund a novel research method. Dr. Robert Lowe, an associate professor of emergency medicine at the university, was chosen to receive Intel-OCTRI pilot project funding to support the development of multi-sensing devices with health applications. This synergistic project between OCTRI and Intel will serve as a model for stimulating collaborations that will not only lead to new devices to improve human health, but will also provide clinical researchers with increased access to private companies at the cutting edge of technology.

Lowe's interdisciplinary investigative team, comprised of researchers from neurology, emergency medicine, the Oregon stroke center, organic chemistry, and emergency services, will monitor two groups of patients outside of the hospital setting: 1) patients at high risk of atherosclerotic disease (e.g., stroke and myocardial ischemia) and 2) diabetics at risk of hyper- or hypoglycemic emergencies. The proposed sensing devices couple state-of-the-art wireless and mobile technology with sensors to enable earlier detection and treatment of these common and life-threatening diseases.

Advancing Cancer Research Through Novel Approaches

Dr. Gary Thomas, a senior scientist of the Vollum Institute at Oregon Health & Science University (OHSU), is receiving pilot funding for a project, entitled "Role of PACS-2 in colorectal cancer." The long-range goal of this research is to determine the role of the novel sorting protein, PACS-2, in regulating apoptosis and colorectal cancer, a leading cause of cancer death in the United States.

Colorectal cancer results from genetic instability. Dysregulating proliferative and apoptotic genes stimulate tumor genesis, but the molecular details of this transformation pathway remain elusive. OHSU recently reported that PACS-2 is a multifunctional protein that integrates endoplasmic reticulum (ER) trafficking with apoptotic pathways. Its function is lost in up to 40 percent of sporadic colorectal cancers. In healthy cells, the protein regulates ER trafficking, but preliminary data show that in response to apoptotic inducers, it binds to proapoptotic Bcl2-family members and translocates them to mitochondria to trigger apoptosis.

This pilot study is determining the extent to which the loss of PACS-2 contributes to the onset and severity of colorectal cancer. Thomas hypothesizes that the dysregulated expression of this protein accelerates the generation of tumors in colorectal cancer. The first study aim is to determine when PACS-2 is lost during the adenoma-carcinoma sequence. The second aim is to study the effect of targeted disruption of the mouse PACS-2 gene on the onset and severity of adenocarcinomas. These results will illuminate how loss of this protein contributes to colorectal cancer.

The Rockefeller University

Supporting Research in a New Class of Drugs for Alzheimer's Disease

Research by Dr. Marc Flajolet in the laboratory of Nobel laureate Dr. Paul Greengard, director of The Rockefeller University Fisher Center for Alzheimer's Disease Research and a faculty member of the university's CTSA, may result in a new class of drugs for Alzheimer's disease. The prevalence of this disease, which currently affects more than 5 million Americans, is expected to soar to 7.7 million people by 2030 if effective treatments or cures are not found.

Flajolet has identified a set of compounds that can block the production of amyloid beta, the rogue protein that accumulates in the brains of people with Alzheimer's disease. While most current drugs being tested for the disease cause serious side effects in patients, the new compounds Flajolet has identified might be safer because they use an entirely different mechanism to block amyloid beta production.

If the preclinical studies that Flajolet is conducting continue to yield positive results, he may soon be in a position to test his compounds in clinical trials within the university's CTSA, which includes a hospital devoted exclusively to medical research. The facilities for patient-oriented studies offered by the CTSA are particularly critical for basic researchers like Flajolet who are engaged in clinically

relevant research but do not have the necessary skills or resources for carrying out clinical trials.

Web Site: www.rockefeller.edu/ccts

University of California, Davis

Advancing Research Through Multidisciplinary Collaboration and Novel Approaches

The University of California, Davis (UC Davis) Clinical and Translational Science Center's (CTSC) pilot grants cross many disciplines and include new technologies; telemedicine approaches; outreach efforts; and novel collaborations among the Schools of Medicine and Veterinary Medicine, the UC Davis Genome Center, Lawrence Livermore National Laboratory, the Center for AIDS Research, Education, and Services, the Tuberculosis Control Program in Sacramento County, the private sector, and others. The recipients work closely with the CTSC for additional resources to support their collaborative research programs.

Examples of pilot projects funded in 2006:

- Dr. Nicholas Kenyon, assistant professor of pulmonary and critical care medicine, is studying L-arginine therapy in asthma. L-arginine is a natural amino acid that may help decrease the intensity of asthma episodes in sufferers.
- Dr. Debora Paterniti, associate director of the Center for Health Services Research and associate professor of sociology, will focus her work on disseminating information on methods to reduce disparities in mental health services for minority and rural populations.
- Dr. Lorenzo Rossaro, professor and chief of gastroenterology and hepatology, is testing the safety and effectiveness of telemedicine consultations in treating patients with hepatitis C viral infection.
- Dr. Mark Zern, professor of internal medicine, is developing diagnostic tools for non-alcoholic steatohepatitis (a common form of liver disease).
- Dr. Kathryn DeRiemer, assistant adjunct professor for public health sciences, will further her work in diagnosing the infection and progression of tuberculosis through the use of a novel immunoassay system.

Examples of pilot projects funded in 2007:

- Dr. Laura Marcu, associate professor of biomedical engineering, is working with surgeons in the Department of Otolaryngology to evaluate a novel optical spectroscopy/imaging device for intraoperative identification of tumor versus normal tissue during surgical resection of head and neck squamous cell carcinoma.
- Dr. Ramsey Badawi, assistant professor of radiology, is working with others in the Departments of Radiology and Biomedical Engineering and the Division of Rheumatology to develop molecular imaging procedures to separate responders from nonresponders to molecularly targeted pharmaceuticals in rheumatoid arthritis treatment.
- Dr. Joy Melnikow, professor of family and community medicine, is collaborating with a faculty member from the Department of Sociology to conduct focus groups to understand the HPV vaccine needs of low-income, low-literacy parents and their middle school (11- to 13-year-old) daughters to help reduce disparities.
- Dr. Mark Underwood, assistant professor of pediatrics, is collaborating with faculty from the Departments of Medical Microbiology and Immunology, Viticulture and Enology, and Chemistry, and the Medical College of Wisconsin on a pilot study in premature infants to determine if components of human milk lead to increased growth versus control infants fed formula.

Web Site: www.ucdmc.ucdavis.edu/ctsc

University of California, San Francisco

Generating a Pipeline of Translational Researchers Through Critical Training

The University of California, San Francisco (UCSF), is creating “a smorgasbord” of curriculum and approaches, according to Dr. Jeffrey Martin, who heads the training program there. In addition to a two-year comprehensive master’s degree in clinical and translational research, UCSF offers a comprehensive one-year certificate program and an eight-week summer clinical research workshop. These programs address common challenges in M.D. or Ph.D. training, from expertise in epidemiology and biostatistics to knowledge of ethical and regulatory issues.

In addition to existing programs, UCSF is developing a one-month course on designing clinical research aimed primarily at clinical residents, “who heretofore have generally been forgotten in terms of induction and maintenance of research skills,” explains Martin. The university also has plans to

develop discrete tracks within the existing master’s program in the two NIH-defined areas of translational research: 1) laboratory to human subjects and 2) evidence to clinical and public health practice.

This year alone, UCSF training programs support 30 master’s students, 26 certificate candidates, and 132 summer workshop participants. Martin attributes this strong interest to a high level of rigor in the programs and an emphasis on practical application. “We want our scholars to understand the process of knowledge creation from start to finish with firsthand experience in all the steps along the way.”

Integrating and Consolidating Services to Streamline the Research Process

The University of California, San Francisco’s (UCSF) Clinical and Translational Science Institute (CTSI) is facilitating collaboration among the university’s centers and departments to provide researchers with comprehensive and accessible services. Examples include creating a central grant-making organization, developing a cross-campus core services database, and continuing to integrate resident research training with existing medical education programs.

Working with leaders of other clinical and translational research units at UCSF, CTSI has led an effort to review, prioritize, and consolidate overlapping clinical and translational research core activities so that they can be more readily and broadly available to all. A Web-based, searchable database of core campus services is being developed. The database will have a search feature to make it easier to use for researchers. CTSI’s grant-making program is working with several other institutional funding programs to create an umbrella funding organization. This new funding center will allow researchers to search for funding opportunities through a common portal and have their grants reviewed through a more streamlined, rigorous, and fair process.

CTSI staff members are working to better integrate new residency training programs into existing medical programs by meeting with all of the university’s clinical department chairs and program directors to survey resident education needs. The new program has already enrolled 50 residents in its first year into existing medical education at UCSF.

Web Site:

http://medschool.ucsf.edu/news/features/research/20060911_CTSI_overview.aspx

University of Pennsylvania

Sharing Regulatory and Administrative Work Speeds Clinical Trial

Physician-scientist Dr. Stephan Grupp at the Children’s Hospital of Philadelphia is developing a vaccine against

neuroblastoma that could improve the odds of surviving this common and deadly cancer among children. Using resources provided through the CTSA at the University of Pennsylvania (Penn), Grupp was able to enlist the help of a collaborating institution — the Dana-Farber Cancer Institute in Boston — to complete his studies more rapidly.

Before Grupp could test his cancer vaccine on patients, he had to find a way to “rescue” their immune systems, which were severely weakened by rounds of intensive chemotherapy and radiation. In a clinical trial funded by the National Cancer Institute, Grupp and colleagues at Penn collected blood cells from neuroblastoma patients at the time of diagnosis, coaxed these cells into dividing and multiplying outside the body, and then transplanted them back into the patients after they had received therapy. Preliminary data suggest that these cells are fully functional and allow a patient with a devastated immune system to mount an immune response to a vaccine.

To finish the current trial twice as quickly, Grupp decided to collaborate with investigators at Dana-Farber, but to do so he had to complete extensive regulatory and administrative paperwork. Penn’s CTSA provided staff with the necessary skills and resources to accomplish the arduous task. The payoff is that when the current clinical trial is completed in the fall of 2007, Grupp will have a chance to move forward with another trial to test his new cancer vaccine. And if he and investigators at Dana-Farber decide to collaborate on the second trial, the groundwork has already been laid.

Bridging the Gap Between Pediatric and Adult Medicine

The University of Pennsylvania and Children’s Hospital of Philadelphia General Clinical Research Centers have merged to form the Clinical and Translational Research Center (CTRC), which has markedly expanded and integrated its repertoire of core services, a program of grant support for beginning investigators, and a focus on detailed elicitation of phenotype in the exploration of genetic and environmental factors that contribute to variability in response to therapeutics. An emphasis of the CTRC is also to support research programs that aim to span the artificial divide between pediatric and adult medicine. A common CTRC application will be merged into the electronic institutional review board application at both institutions, thereby streamlining the regulatory submission process for researchers.

Supporting Research on Diseases and Conditions Affecting Children

Pilot funding through the university’s CTSA are supporting research on diseases and conditions (such as autism) affecting children. A new initiative at the University of Pennsylvania/Children’s Hospital of Philadelphia is the creation of the Center for Autism Research. This new center

coordinates, sponsors, and supports all autism-related research at both of these institutions, enabling interdisciplinary collaborations among researchers, facilitating translational research, and furthering community-based research. The scope of the new autism center will include basic and clinical research as well as community-based research that will directly address the issues affecting children with autism and their families in the Philadelphia metropolitan area—the fifth largest urban area in the United States. The staff consists of 15 university faculty members (from nine departments and three schools), each of whom shares a strong interest in autism research and abiding commitment to this patient population.

Web Site: www.itmat.upenn.edu

University of Pittsburgh

Connecting Researchers with Potential Study Participants: Clinical Research Registry

The University of Pittsburgh’s Clinical and Translational Science Institute is developing a clinical research registry to link researchers with potential study participants. This database will include people willing to participate in clinical research and an ongoing list of studies (currently 5,600) being conducted through the university and its medical center. The database will be embedded in the medical center’s electronic health record system, giving researchers potential access to people in the medical center’s 350 outpatient locations and 19 hospitals, which account for more than 3 million outpatient visits and more than 167,000 hospitalizations each year.

Promoting Research Collaboration Through Information

Academic and other research institutions are knowledge-intensive, but their structure does not always facilitate application into clinical practice. One obstacle is the disincentive for information sharing, both within and between institutions. To help improve the situation, the University of Pittsburgh, Oregon Health & Science University, and Columbia University have begun to collaborate on the development of online research communities at their respective institutions. The goal is to help researchers find collaborators, provide targeted information, and eventually link to the external world of biomedical science.

Web Site: www.ctsi.pitt.edu

University of Rochester School of Medicine and Dentistry

Helping to Advance Emergency Medicine

An innovative project, led by the University of Rochester's Department of Emergency Medicine, is connecting emergency rooms throughout upstate New York to conduct clinical and translational research. Given the nature of emergency medicine, high-quality clinical and translational research is rarely carried out in this discipline. This network will provide the infrastructure for research that aims to reduce mortality and morbidity associated with acute illness and injury. The lead agency for this project is the University of Rochester's Department of Emergency Medicine. Partners include Upstate Medical University of Syracuse, Guthrie Healthcare System, which serves northern Pennsylvania and New York, Bassett Hospital in Cooperstown, Erie County Medical Center in Buffalo, and Albany Medical Center.

Speeding Exchange and Evaluation of Imaging Data

The Upstate Imaging Biomarkers Consortium is an innovative collaboration between radiologists and surgical oncologists at several upstate New York cancer research and treatment facilities that will serve as a large "virtual imaging laboratory." Researchers will be able to exchange and critically evaluate imaging data with the goal of developing standardized criteria for evaluating a patient's response to existing and emerging cancer therapeutics. The long-range goal of the consortium is to link the upstate region's cancer centers to the cancer Biomedical Informatics Grid™ (caBIG™), a national effort supported by the National Cancer Institute. Roswell Park Cancer Institute in Buffalo will serve as the lead agency, in partnership with the University of Rochester.

Web Site: www.urmc.rochester.edu/ctsi/index.cfm

University of Texas Health Science Center at Houston

Helping Researchers Resolve Issues from Protocol Design to Budgets

As a surgeon well versed in laboratory studies, but not so much in patient trials, Dr. Emily Robinson is taking advantage of a new program at the University of Texas Health Science Center at Houston that shepherds researchers through the clinical research process. The new program helps researchers use the services of the clinical research units within the university's Center for Clinical and Translational Sciences. In the past, applying for these services was time consuming, requiring separate applications for approval of the institutional review board, Memorial

Hermann Hospital–Texas Medical Center, and the clinical research unit. To streamline the process, these applications have been combined.

To further facilitate research implementation in the clinical research units, scientists can now use the center's SPARK (Scientific Partners Advancing Research Kickoff) program to resolve problems that may delay approval, including such issues as protocol design, human subjects, and budgets. Since May 2007, at least 10 researchers have used the SPARK program. Robinson, who is proposing a cancer study, says, "The feedback from the SPARK team will help me avoid delays getting my study approved and implemented in the clinical research unit." Joy Lilljedahl of the Center for Clinical and Translational Sciences added, "Scientists were having to go back and forth to resolve issues. Now, we work together to resolve issues."

Crossing Traditional Academic Boundaries, Providing Access to a Minority Research Cohort Along the Texas-Mexico Border

Researchers and resources are being matched at think tank retreats organized by the Center for Clinical and Translational Sciences at the University of Texas Health Science Center at Houston to identify broad research areas that cross traditional academic boundaries.

At a recent retreat, Dr. James Katancik, a periodontist within the university's dental branch who has an interest in diabetes and gum disease, learned that the center includes a clinical research unit along the Texas-Mexico border—where one in five of the predominantly Mexican-American population has diabetes. Katancik took advantage of an opportunity to visit this research unit at the Brownsville facility. Here, Dr. Joseph McCormick and his colleagues were celebrating the opening of their new, larger clinical research facility at the Valley Baptist Hospital and the achievement of the 5-year recruitment of a diabetes cohort study involving 2,000 Mexican-American participants from the local community.

"If I decide to extend my study of gum disease to the Hispanic community, this facility will be a tremendous resource," Katancik said, adding, "For me, the retreat was enormously helpful." McCormick commented, "We have a facility where researchers can ask scientific questions that require community-based research by accessing our minority cohort (Cameron County Hispanic Cohort) and expect to get solid data." The extensively documented cohort is a key part of the Hispanic Health Research Center that was instrumental in developing the infrastructure that supports the clinical research unit. Combined with a strong outreach program, the cohort provides ready access to this minority population.

Benefiting from Multimedia Health Curriculum

When his grandfather had a heart attack, a junior high school student knew what was happening and was able to help. The week before, he had learned how the heart works from his science teacher Ro Luecken. The boy said he was able to understand what the doctor at the hospital was talking about, because he had learned the information in class. He was also able to explain the situation to his parents, who spoke limited English.

“This was music to my ears,” says Luecken. “It shows how important it is for students to learn about the health industry in class and to be able to associate it with things that happen in their everyday lives.”

Luecken’s cardiac presentation was based on supplementary curriculum produced by the University of Texas School of Public Health HEADS UP project, which is supported by an NIH Science Education Partnership Award and the Center for Clinical and Translational Sciences at the University of Texas Health Science Center at Houston. The university created six multimedia curriculum modules covering such topics as genetics, diabetes/cardiovascular disease, and nutrition and provides them free of charge to the Spring Branch Independent School District. “I’ve just begun to recognize the value of having this type of curriculum in the classroom,” says Luecken.

Web Site: www.uthouston.edu

Yale University

Impacting Research: Childhood Obesity

A CTSA-funded study on the effects of a weight management program on body composition metabolic parameters in overweight children was published in the June 2007 issue of *JAMA*. The research was conducted by lead author Mary Savoye, Dr. Sonia Caprio, and colleagues from Yale University and Hadassah Hebrew University School of Medicine, Jerusalem, Israel.

Pediatric obesity has escalated to epidemic proportions and leads to an array of comorbidities, including type 2 diabetes. Because most overweight children become overweight adults, this chronic condition results in serious metabolic complications by early adulthood, highlighting the need for effective pediatric interventions.

The study consisted of a one-year randomized controlled trial conducted between May 2002 and September 2005 in which 209 overweight children were recruited to participate in the Yale Bright Bodies Weight Management Program, a family-based, intensive lifestyle intervention that has been specially tailored for the needs of inner-city minority children. Participants randomized to the weight management

group attended the program twice a week for six months and then every other week for an additional six months. The program consisted of supervised exercise and nutrition/behavior modification instruction, with participants and caregivers attending classes. The control group participants were seen in the pediatric obesity clinic every six months and received diet and exercise counseling.

Body mass index (BMI), percent body fat, and total body fat were reduced in the weight management group, but increased in the control group. Mean fasting plasma insulin concentration and the homeostasis model assessment of insulin resistance (HOMA-IR), which was used to measure insulin sensitivity, also fell in the weight management group but increased in the control group. The results show that simple education about the health risks of obesity and routine counseling about diet and exercise are insufficient to prevent increases in BMI, whereas the improvements seen with the Bright Bodies program were sustained during the second six-month maintenance phase, with the gap between the two groups widening. Although the program required a substantial commitment in time and effort, 71 percent of the weight management group completed the entire 12-month intervention.

The results of this study refute the widely accepted view that changing the lifestyle of overweight children is futile and will be disseminated to pediatric clinicians, health organizations, and the community so that such interventions can be implemented more broadly.

Collaborating with Community Yields Health Priorities

In addition to creating networks and strengthening relationships among business and community-based leaders; government officials; health care providers; and Yale faculty, researchers, and senior administrators, a recent conference demonstrated a commitment to improving the health of the community and may well serve as a model for other urban centers that strive for productive community-university relationships.

In May 2007, more than 70 leaders from New Haven, Conn., and Yale University gathered to participate in a conference to determine how Yale and New Haven could work together to advance clinical research and, in turn, improve the community’s health. The Future Search Consensus Conference, which was sponsored by the Community Alliance for Research and Engagement (CARE) and funded by the Yale CTSA and the City of New Haven, had the goal of answering the following question: How can New Haven and Yale University obtain and use research-related resources to advance clinical research that will improve the health care and strengthen the health of our community?

Conference participants engaged in brainstorming sessions, using their expertise to find common ground and identify short-term (three-month) and long-term (three-year) goals to

enhance health in New Haven. They discussed key health issues facing the community today and formulated next steps for the coming year to help.

Some of the priorities that emerged included:

- Establishing a workgroup composed of senior Yale faculty and community leaders to develop a set of ethical principles of engagement for developing and implementing collaborative research proposals. As a result of the conference, the group has been meeting regularly and expects to release guidelines in the spring of 2008.
- Establishing an inclusive and transparent governance structure for CARE to foster cross-sector collaboration on priority city health issues.

- Soliciting and funding community-university pilot research projects, giving preference to projects that focus on promoting health equity.
- Communicating research results and relevant health information via accessible community forums, newsletters, Web site content, and outreach activities.
- Increasing access to training and research support to enhance the capacity of community agencies and practitioners to conduct research.

Web Site: www.ycci.yale.edu

CTSA Clinical & Translational Science Awards

For CTSA programmatic information, contact:

Anthony R. Hayward, M.D., Ph.D.
Director, Division for Clinical Research Resources
National Center for Research Resources
National Institutes of Health
One Democracy Plaza, Room 906
6701 Democracy Boulevard, MSC 4874
Bethesda, MD 20892-4874
301-435-0790; Fax: 301-480-3661
E-mail: HaywardA@mail.nih.gov

For CTSA communications information, contact:

Kameha R. Kidd, Ph.D.
Health Science Policy Analyst
Office of Science Policy and Public Liaison
National Center for Research Resources
National Institutes of Health
One Democracy Plaza, Room 971
6701 Democracy Boulevard, MSC 4874
Bethesda, MD 20892-4874
301-402-9765; Fax: 301-480-3558
E-mail: KiddKa@mail.nih.gov