How do you mend a broken heart?

Drs. Richard Smalling and Ali Denktas are taking a leading role in two trials aimed at finding innovative ways to treat heart disease. Stories on pages 2 and 4.
A cardiologist who practices at Memorial Hermann-Texas Medical Center has taken a lead role in clinical tests of a procedure that could provide a minimally invasive option to open heart surgery for patients suffering from mitral valve regurgitation (MR).

Dr. Richard Smalling is a principal investigator in Evalve’s EVEREST trials. The research is designed to assess the feasibility of repairing a patient’s mitral valve by clipping its two leaflets together using a small device known as a MitraClip.

Memorial Hermann-Texas Medical Center is the only site in Houston – and just one of two in Texas – to enroll patients in the study.

Smalling, the J. Brent Sterling Professor of Cardiovascular Medicine at The University of Texas Medical School at Houston, first performed the innovative procedure in December 2005 as part of a Phase I Investigational Device Trial. He said the results so far have been promising.

"It’s early," he added, “but we are encouraged. The patient did beautifully, and we’re seeing a dramatic improvement in symptoms.”

Data from centers that have participated in the EVEREST trial support that assessment:
- Of 47 patients treated using the MitraClip procedure, only 4 percent experienced a significant adverse effect at 30 days.
- Of the 27 patients who reached a one-year follow-up, none experienced an increase in MR severity.
- 93 percent of patients who experienced a significant reduction in MR at one month after treatment maintained that improvement at one year.
- 75 percent of patients who received the clip did not require open heart surgery.

An “Impressive” Alternative To Surgery

The mitral valve is a one-way blood flow regulator that separates the left atrium, which collects blood from the lungs, from the left ventricle, which pumps the oxygenated blood out to the body. It has two flaps, or leaflets, that open and close together, similar to a pair of swinging doors. When the heart beats and pumps blood, the flaps swing shut to prevent blood from going back – regurgitating – into the left atrium.

In patients with MR, the valve does not close properly. Blood flows backward into the left atrium during heartbeats, decreasing blood flow to the body. This places an extra burden on the heart and lungs, causing the left ventricle to pump harder and resulting in ongoing and increasing damage that could lead to congestive heart failure, stroke, irregular heartbeat, and sudden death.

Open heart surgery has been the typical approach to mitral valve repair. In the operation, which usually lasts several hours, the heart is stopped and blood is circulated through a heart-lung machine. After the procedure, patients remain hospitalized for four to 10 days typically.

But the technique Smalling is testing represents a sharply different approach. It is less invasive, allows the heart to remain beating on its own during the procedure, and reduces length of hospital stay.
"This has the potential to be an effective, minimally invasive alternative that can also speed up the recovery process," he explained. "Patients can go home the next day and return to their regular activities in less than a week. It's pretty impressive."

"Complicated but Clever"

The procedure’s roots date back to the early 1990s, with a technique called edge-to-edge repair. In this, a portion of the anterior leaflet is sutured to a corresponding portion of the posterior leaflet, creating a point of permanent contact. The valve continues to open on both sides of the suture, allowing blood to flow normally from the left atrium to the left ventricle and assuring that the valve closes properly when blood is pumped from the left ventricle.

The MitraClip approach is designed to replicate the edge-to-edge technique in principle. But instead of using a suture to connect the leaflets, it clips them together in a process that Smalling called “complicated but clever.”

In the procedure, a steerable guide catheter is inserted into the femoral vein through a small puncture in the groin, providing a conduit to access the mitral valve. Then a delivery system is inserted through the catheter, transporting the MitraClip to the valve leaflets and positioning it appropriately. Once in place, the clip is used to grasp and fasten the mitral valve leaflets together in much the same way they were sutured under the edge-to-edge technique.

The benefits of the procedure are significant. By allowing cardiovascular specialists to repair the valve while the heart is still beating, it avoids cardiopulmonary bypass or the need for a thoracotomy or sternotomy. Additionally, the system lets physicians fully reverse all steps prior to clip implantation. So if the cardiovascular specialist is unsatisfied with the initial clip placement, the clip can be repositioned or removed – preserving open heart surgery as an option if necessary.

Other features include:

- A design that captures and retains each leaflet independently, minimizing the potential for clip embolization;
- A commonly used, implant-grade polyester fabric that covers the clip and is intended to promote healing and further anchor the clip to the leaflets; and
- Strong construction that ensures the clip can withstand normal forces exerted upon it during the cardiac cycle.

"An Exceptional Team"

With the Food and Drug Administration’s approval based on the Phase I results, Smalling and his team have moved on to a randomized, rigorous Phase II Pivotal Study. Other institutions participating include Columbia University Medical Center, Brigham and Women’s Hospital, Cedars-Sinai, and Duke University Medical Center.

Smalling said that the involvement of Memorial Hermann in the EVEREST trials demonstrates that the hospital’s cardiovascular services are earning a reputation that goes beyond the Texas Medical Center.

“People are beginning to understand we have pursued, and have begun to develop, an innovative interventional program,” he concluded. “To do that requires an exceptional and exceptionally skilled team – and that’s what we have.”
Memorial Hermann-Texas Medical Center is one of just 10 U.S. facilities participating in a human clinical study trial using adult stem cells to prevent muscle death and repair heart damage in patients who suffered myocardial infarction (MI).

The study aims to assess the safety and preliminary effectiveness of a universal adult stem cell candidate called Provacel™, which was developed by Osiris Therapeutics Inc.

In essence, Provacel helps the heart heal itself. Beyond that, it does not require a patient-specific match. Rather, the adult stem cells – not to be confused with the controversial embryonic stem cells – are mass-produced at the Osiris headquarters in Baltimore, and are then frozen, shipped to hospitals, and stored until needed.

The constant availability of the stem cell product would allow doctors to immediately treat heart attack patients in the acute setting. That is critical to Memorial Hermann, which handles up to 80 percent of the area’s MI – anywhere from 25 to 40 incidents per month.

Dr. Ali Denktas, assistant professor of internal medicine/cardiology at the UT Medical School and the principal investigator in the trial at Memorial Hermann, said Provacel has the potential to “cure the heart” after myocardial infarction.

“When people have a heart attack, the muscle dies,” he explained. “The old dogma is that hearts don’t recover. Actually, the heart can repair itself; there are cells in the bone marrow and the heart that help the recovery. But the natural processes aren’t enough by themselves, so we are looking to give them a ‘boost.’

“That’s what this study is designed to do. If this therapy works, we will have a way to recover cells in the heart and restore cardiac function. If we can do that, we will make the heart stronger, which will have an impact on mortality. Basically, we will cure the heart.”

Fifty-three patients were enrolled in the study, which was undertaken at 10 leading heart centers across the country. It is a randomized, double-blind, placebo-controlled, Phase I clinical trial. Patients were chosen at random to receive either an injection of 0.5 million, 1.6 million, or 5.0 million cultured adult mesenchymal stem cells – that is, Provacel – per kilogram of body weight, or a placebo.

Along with the stem cells or placebo, patients received standard treatment that included techniques to maximize blood flow to damaged areas, pain relief, oxygen, anticoagulants, beta-blockers, nitrates, angiotensin converting enzyme (ACE) inhibitors, and advice on reducing risk factors.

Many experts believe that mesenchymal stem cells (MSCs) have tremendous treatment potential in cardiology. In animal studies, cells injected into the heart muscle following MI have reduced cell death and increased pumping strength. Additionally, research has shown that MSCs can be transplanted from person to person without fear of rejection because they are universally compatible.

The MSCs exist in the bone marrow of adults, where researchers believe they await a chemical “signal” to replace damaged tissue. Depending on which signal they receive, the stem cells can become cartilage, bone, or muscle cells.

While some tissues have the ability to regenerate, others – like the heart muscle – are severely limited in that process. When a human suffers an injury that cannot heal itself, fibrosis occurs; the injury is repaired to some degree, but leaves scar tissue that ultimately reduces an organ’s performance.

The problem is especially acute in heart attacks, in which a sudden blockage of an artery deprives heart muscle of oxygen and blood. The injury and subsequent scarring cause the heart’s efficiency to decline, resulting in congestive heart failure.

Preclinical studies of Provacel indicated that the stem cells responded to signals put out by the heart after MI by going directly to where the injury occurred. Once at that site, they participated in the repair – in effect, derailing the scarring process before it poses a problem.

The ability to treat MI faster poses a critical benefit to the more than 100,000 Americans who suffer a first heart attack each year.

Provacel’s ease of delivery – Denktas equated it to a blood transfusion – is another significant advantage. “It is administered intravenously,” he said. “The process is very simple. No additional percutaneous intervention is required.”

With the Phase I trial complete and positively reviewed by an independent safety board, the Osiris study has been authorized to move on to a Phase II study. That is expected to begin near the end of 2006.
CHANAUD NAMED HEAD OF RESEARCH

Dr. Cheryl M. Chanaud, the new executive director for clinical innovation and research at Memorial Hermann, calls herself “a scientist first and an administrator second.” With her 18-plus years of administrative research experience, accompanied by a variety of leadership roles, it is an apt description.

Chanaud comes to Memorial Hermann from St. Jude Children’s Research Hospital in Memphis, Tenn., where she served four years as vice president for clinical research. She said that the ability to work with a teaching hospital was an important factor in her decision to come to Houston.

“The academic affiliation made it very attractive,” she explained. “This presents a great opportunity to help develop meaningful research programs in a number of areas.”

Those areas include cardiovascular, neurosciences, pediatrics, and cancer, all of which will receive what she termed a “special focus.” But she was quick to point out that the research activities do not begin and end there.

“We cover any disease and specialty area in medicine,” added Chanaud, who has been a Certified Clinical Research Professional since 1999.

While at St. Jude, she helped spearhead an effort in which researchers used the hospital’s data warehouse system to collect and share data from the institution’s Clinical Research Information System and various legacy databases.

The initiative saved time and money by building data “marts” that supported new research studies and was able to accommodate the data capture, analysis, and reporting needs of the hospital’s researchers. It earned St. Jude a 2005 Enterprise Value Award from CIO magazine.

Prior to her service at St. Jude, Chanaud held multiple positions at UT Medical Branch in Galveston, including assistant vice president for research, assistant vice president for clinical trials, director of the office of clinical trials, which she also established, and assistant professor in the department of anatomy and neurosciences.

Chanaud graduated from Colorado State University with degrees in biology and physical science. She went on to earn a master’s in biology from Purdue and a Ph.D. in zoology from the University of Maryland.

In the years between Maryland and UTMB, she worked in a diverse range of capacities. These included visiting scientist at the department of neurobiology and oral biology, University of Groningen in Holland; staff fellow scientist, speech and voice unit, National Institute of Deafness and Communication Disorders; director of research and education with the Paralyzed Veterans of America; health scientist administrator/physiologist at the National Center for Medical Rehabilitation Research; and a regional director of clinical research for UroTherapies.

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- DR. CHERYL M. CHANAUD

Additionally, she owned and published The Spinal Cord Injury Newsletter: Rehabilitation, Recovery, and Research.

During her career, Chanaud has also held numerous positions of responsibility on a broad range of professional associations and hospital committees.

She has provided national leadership to hospitals and academic health centers that conduct human subject research, serving as chair of the Clinical Research Special Interest Group and the Academic Health Center Track for the Drug Information Association. Additionally, she was also a member of the Academic Health Centers Clinical Research Forum, a national group representing 40 U.S. hospitals and universities.

At St. Jude, she chaired the HIV Vaccine Project Management Team, and was a member of the Technology Leadership Group, the Clinical Protocol and Scientific Review and Monitoring Committee, the Institutional Review Board, the Institutional Biosafety Committee, the Research Advisory Committee, and the Protocol Accrual Task Force.

She was similarly involved at UTMB, serving on the HIPAA Policy Work Group, the Research Facilities Planning Committee, the General Clinical Research Center Advisory Committee, the Clinical Research Education Office Committee, and the Institutional Ethics Committee. She also chaired the Clinical Trials Faculty Working Committee.

Chanaud has held three research-related positions at the National Institutes of Health. In addition, she has served as principal investigator on two NIH education grants and one with the Office of Research Integrity at the U.S. Department of Health and Human Services. She has also taught at the graduate and medical school level and been a guest lecturer on federal regulations, good clinical practices, and clinical research ethics for educational seminars throughout the United States.

Her more than 40 presentations to professional and academic audiences have included topics such as:

- Implementation Methods for ICH Good Clinical Practices
- Clinical Research Sponsor Responsibilities
- Educating Clinical Staff in Clinical Research: Computer-Based Learning Focused on Clinical Research Data Acquisition and Data Integrity
- Good Clinical Practices for Pharmacy
- Importance of Clinical Research Documentation
- Overview of Good Clinical Practices
- Financial Management of Clinical Trials
- Clinical Research Risk Management Programs for AHCs
- Ethics and Clinical Research

Beyond all that, she has written or co-written peer-reviewed articles for publications that include *Journal of Neuroscience Letters, Annals of Otology, Rhinology & Laryngology, Experimental Brain Research, Journal of Neuroscience Methods, Journal of Women’s Health, and Journal of Morphology.*
ILRU TARGETS FUTURE HEALTH CRISIS

When Lex Frieden talks about the need to develop a strategy for assisting people with disabilities during the next decade, he's not simply interested in raising public awareness of the issue in the future.

He wants to avert a healthcare crisis now.

“We have data showing that each day for eight years following January 1, 2012, ten thousand people will reach retirement age,” said Frieden, senior vice president of The Institute for Rehabilitation and Research (TIRR). “Between 2012 and 2020, 80 million people will be over retirement age – and half will have disabilities of some type.

“There are not enough nursing homes to accommodate them. They’re part of the ‘me generation’ that wants to be responsible for themselves, but there’s no infrastructure to provide care for them in their own homes, and nursing homes are already full – many with younger people who could be back in the community. So what should we do? It is a huge concern.”

It’s also a concern – one of several – that Frieden’s research and that of the Independent Living Research Utilization program (ILRU) is working to address.

Established in 1977, ILRU is a national center for information, training, research, and technical assistance in the area of independent living. It is part of TIRR, the renowned medical rehabilitation facility that recently consolidated with Memorial Hermann Healthcare System.

The program’s research activity, which to date has earned almost $56 million in funding, focuses on three primary areas: policy change and technical assistance in regard to the Americans With Disabilities Act (ADA), which Frieden helped to conceive and draft; long-term care services, particularly community-based services; and independent living.

“Our research is all about affecting environmental, physical, and attitudinal change,” says Frieden, a quadriplegic due to spinal cord injury, “and changing public policy to assure that people with long-term care needs can function in the community as well as anyone else.”

A centerpiece of that approach is ILRU’s effort to ease – and potentially erase – the looming crisis over how to provide extended, home-based care for individuals who do not need to be placed in nursing homes.

“There are critical questions,” Frieden explains. “How do we get them out of these ‘warehouses’ and into the mainstream? How do we ensure that people confronted with disabilities have a choice of moving into the institutional care setting or into the home care setting? "To the extent that we recognize there are answers to these questions, we can solve some of the challenges. And that is our challenge: Finding the answers."

The search is being assisted in part by $8.6 million in grants from the Centers for Medicare and Medicaid Services (CMS).

ILRU has been deeply involved in the Real Choice initiative, which CMS says is designed to “help states and others build the infrastructure that will result in effective and enduring improvements in community-integrated services and long-term support systems that enable individuals of all ages to live in the most integrated community setting suited to their needs, to have meaningful choices about their living arrangements, and to exercise more control over the services they receive.”

In its role, ILRU provides technical assistance to 52 Real Choice grantees through the Community Living Partnership. A three-year program that is also funded by CMS, the Partnership focuses on issues relating to system change in community living.

“The hope is that if we can help states change their policies and practices now, we’ll presumably be able to deal with this issue in the next eight to 10 years,” Frieden says.

While helping manage the long-term care problem is a forward-focused strategy for ILRU, the issue of compliance with the Americans With Disabilities Act is current and ongoing. And although Frieden believes there have been advances on that front, he says there is still room for progress.

“It’s clear to us that large businesses and large communities have made a substantial effort to comply with the ADA,” he explains. “But smaller businesses have difficulty understanding their obligations and the requirements of the law. A major reason is resources; they just don’t have the money. So we help them interpret their obligations.”

To do that, ILRU is part of a multimillion-dollar program funded by the U.S. Department of Education that offers technical assistance regarding the rights of – and how to accommodate – people with disabilities.

By calling a toll-free number (800-949-4232), businesses, communities, schools, and individuals can receive a broad range of advice and guidance. Frieden estimates the line receives about a thousand calls a month from this region, which consists of Texas and contiguous states, making it the second most active of the 10 U.S. centers.

“We get a lot of questions about compliance and requirements,” he adds. “Some are very specific, like a hotel owner asking about whether he has enough rooms that are accessible to people with disabilities.
Others have to do with employment policies. It varies a great deal."

Those calls have helped ILRU develop a body of knowledge and technical assistance that has been translated to the web, too. Every month, the organization produces between one and four webcasts that are distributed nationally and then archived for continuing access.

ILRU’s third research focus is independent living, an area that has grown significantly over nearly three decades.

Today, the organization works with about 400 centers in communities nationwide to develop advocacy, peer counseling, and personal assistance programs that are run by people with disabilities. That is a dramatic increase from 1978, when the program began with just five.

“We’re the technical assistance and research center for all 400,” Frieden says of the program, which is funded through a grant from the U.S. Rehabilitation Services Administration. “We do everything, including answering questions from government and members of Congress on a weekly basis.”

Frieden’s commitment to these and other issues that drive ILRU’s research date back to the 1970s.

He served as a consultant to the U.S. House Committee on Science and Technology from 1976 through 1978, and prepared the background paper on Community and Residential Based Housing for the White House Conference on Handicapped Individuals in 1977.

From 1984 to 1988, he served as executive director of the National Council on the Handicapped, where he was instrumental in developing the ADA. From 1989 to 1990, he represented the United States on a disability and employment panel at the Organization for Economic Cooperation and Development in Paris.

In 2002, Frieden was appointed by President Bush and confirmed by the U.S. Senate as chairperson of the National Council of Disability, an independent federal agency that grew out of the Council on the Handicapped. It is charged with making recommendations on disability policy issues to the president and congress.

Along the way, he has written numerous books and papers, headed various national and international organizations, won some prestigious awards, and helped organize groups such as the American Coalition of Citizens with Disabilities, the Coalition of Texans with Disabilities, and the Houston Coalition for Barrier Free Living.

Through it all, his commitment to the cause of the disabled – whether through research, education, or public awareness – has never wavered. And for good reason:

“I believe we can make a difference. I believe we can impact healthcare outcomes by ensuring that people who become disabled or cannot fully recover from their disabilities can still be functional, happy citizens enjoying a full quality of life in the community.”

He’s glad to have the opportunity to pursue his goals in association with the Memorial Hermann Healthcare System, too.

“The Memorial Hermann Healthcare System is the only healthcare provider in the Medical Center that truly regards itself as a community system,” he says. “Its willingness and commitment to reach out is helping patients achieve the highest possible quality of life.”

"THE HOPE IS THAT IF WE CAN HELP STATES CHANGE THEIR POLICIES AND PRACTICES NOW, WE’LL PRESUMABLY BE ABLE TO DEAL WITH THIS ISSUE IN THE NEXT EIGHT TO 10 YEARS,” FRIEDEN SAYS.

- LEX FRIEDEN

The Memorial Hermann Center for Clinical Innovation and Research (MHCCIR) is developing a new database that is aimed at linking physicians with the companies and institutions that fund research. This will enable the center to take a more proactive approach to informing physicians of studies involving new products and devices that they may be interested and participate in.

Interested physicians are encouraged to provide the MHCCIR with relevant information, such as credentials, research history, and CVs. The information will allow the center to target specific areas of interest, so that physicians may be contacted regarding potential new clinical trials.

This presents an opportunity to increase the likelihood that the Memorial Hermann hospitals will be used as a Phase I – IV clinical site.

The construction of the database will be phased in by service line, beginning with cardiology and cardiovascular physicians, drugs, and devices.
NIH RENEWS FIVE-YEAR, $2 MILLION GRANT FOR UCRC “RESEARCH INFRASTRUCTURE”

The National Institutes of Health has renewed a five-year competitive grant to the University Clinical Research Center (UCRC) in a move that reflects the “strong relationship” between the Health Science Center at Houston and Memorial Hermann-Texas Medical Center.

The grant, from NIH’s National Center for Research Resources, is for $2 million annually and comes at a time when the agency is cutting back support for General Clinical Research Centers (GCRC) nationally.

Madelene J. Ottosen, MSN, RN, nurse manager at UCRC, attributed the renewal to three primary factors.

“Our strong relationship with Memorial Hermann was a huge reason,” she explained. “The hospital has given us a tremendous amount of support, including expansion of our clinical space, and that was critical to the decision.”

Another key determinant was UCRC’s ability to deliver on its promises.

In applying for renewal, centers are evaluated not only based on their plans for the coming five years but also on how well they accomplished the goals of the previous five years.

“There is a big accountability factor involved,” Ottosen continued, “and we showed that we did what we said we’d do. That made a difference.”

Finally, she credited the efforts of Dr. Pablo Okhuysen, the program director. “He was key in writing, promoting successful collaborations, and presenting a very impressive grant application.”

As a part of the new Center for Innovation and Research at Memorial Hermann, the renewal of the UCRC represents an integral component in creating a comprehensive research network to position Memorial Hermann as a center of research excellence.

The Center for Research Resources provides laboratory scientists and clinical researchers with the environments and tools they need to understand, detect, treat, and prevent a wide range of diseases.

Grants to GCRCs support the components considered essential to clinical research, including operating expenditures, hospitalization and ancillary laboratory costs, and salaries of key personnel – what Ottosen called “research infrastructure.”

The grant awarded to UCRC will be used for:
- Operational support of the center’s clinical space on 3 Robertson
- 9.5 clinical positions including registered nurses and support staff
- Administrative support staff
- A clinical ethicist for patient advocacy
- Biostatistician
- Data management and informatics manager and support
- Bionutritionist/dietitian
- A genetics core laboratory
- Laboratory and diagnostic tests needed in the clinical studies

Since its inception, the UCRC has conducted more than 300 clinical trials, evaluating new cutting-edge treatment modalities and interventions that would otherwise not be available to patients within Memorial Hermann.

Currently, the UCRC collaborates with over 100 clinician scientists in primary areas of research such as cardiology and cardiovascular disease, endocrinology, neurology, infectious disease, rheumatology, oncology, dental and craniofacial conditions, substance abuse, pediatrics, neonatology, and hematology.

To find out more information about the UCRC, access its website at http://www.uth.tmc.edu/uth_orgs/crc/, or call the main number at 713-704-4137.

“OUR STRONG RELATIONSHIP WITH MEMORIAL HERMANN WAS A HUGE REASON,” OTTOSEN EXPLAINED. “THE HOSPITAL HAS GIVEN US A TREMENDOUS AMOUNT OF SUPPORT, INCLUDING EXPANSION OF OUR CLINICAL SPACE, AND THAT WAS CRITICAL TO THE DECISION.”

- MADELENE J. OTTOSEN
CONSOLIDATION CREATES “ONE-STOP SHOPPING” FOR RESEARCH

With the merging of the University Clinical Research Center (UCRC) and the Memorial Hermann Research Department on the third floor of Robertson Pavilion, the TMC campus is now able to offer “one-stop shopping” for research.

The consolidation, a two-year process that was completed this spring, provides a new, updated space for research that includes:

- In-patient rooms that are state-of-the-art for compliance with the Americans With Disabilities Act
- More space for labs and staff
- A waiting room
- Renovations consistent with the latest code requirements of the Texas Department of Health
- Special facilities for bariatric patients

Donna Grayson, administrative director of research, said that the consolidation was aimed at enhancing inpatient services as well as keeping the hospital competitive in the research arena.

“In our previous location (6 Robertson), we didn’t have the inpatient capabilities, and that limited the kinds of studies we could do,” she explains. “At the same time, we needed improvements that would allow us to keep pace with other research facilities.

“So by bringing UCRC and the Hermann Research Department together in one location, we achieved two important goals – and significantly increased our research presence.”

That presence was reinforced by the National Institutes of Health’s decision to renew UCRC’s grant at a time when the agency was reducing funding for clinical research centers.

“It’s a great program and the renewal shows a strong commitment to UT,” Grayson said. “I also believe that the institutional support from both Memorial Hermann-Texas Medical Center and UT played a key part in the renewal as well.”

SOUTHWEST’S VISION BECOMING REALITY

Memorial Hermann Southwest Hospital cancer program has a vision to develop a community-based clinical research program; the vision is becoming a reality. The effort has been spearheaded by Dr. Sam Axelrad, urology, who is serving as chair of the Cancer Research Committee at Southwest.

The addition of Julia Powers, RN, MSN, to the Cancer Service Line has laid the groundwork for a fully functional cancer research team at Southwest. Powers comes to Memorial Hermann with 20 years of research experience in Phase I-IV and bioequivalency clinical trials.

Memorial Hermann Southwest recently had its first official research committee meeting this past month. There are several new clinical research protocols under consideration or in the development process. Some of these protocols will be collaborative efforts with other Memorial Hermann campuses such as Memorial Hermann-Texas Medical Center.

Regulatory items such as the IRB process and SOP development were also discussed. Powers will be on the committee for system-wide SOP development along with other research personnel within the system. Development of a training program on The Successful Clinical Trial will be starting soon. The program will provide orientation and training to the novice researcher as well as serve as a refresher for those who need their research skills revitalized.

For additional information, please contact Powers at 713-456-4011.

“IN OUR PREVIOUS LOCATION (6 ROBERTSON), WE DIDN’T HAVE THE INPATIENT CAPABILITIES, AND THAT LIMITED THE KINDS OF STUDIES WE COULD DO,” GRAYSON EXPLAINS. “AT THE SAME TIME, WE NEEDED IMPROVEMENTS THAT WOULD ALLOW US TO KEEP PACE WITH OTHER RESEARCH FACILITIES.”

- DONNA GRAYSON

“SO BY BRINGING UCRC AND THE HERMANN RESEARCH DEPARTMENT TOGETHER IN ONE LOCATION, WE ACHIEVED TWO IMPORTANT GOALS - AND SIGNIFICANTLY INCREASED OUR RESEARCH PRESENCE.”

- DONNA GRAYSON
$36 MILLION GRANT TO SUPPORT COLLABORATIVE WORK BETWEEN UTHSC-HOUSTON, MEMORIAL HERMANN HEALTHCARE SYSTEM

A $36 million federal grant will enable The University of Texas Health Science Center to further its collaborative work with the Memorial Hermann Healthcare System and expand the University Clinical Research Center at the system’s Texas Medical Center campus.

Memorial Hermann’s role as a participating partner is to support and facilitate the research programs by involving Memorial Hermann hospitals or clinics, private practitioners and research personnel. This deepening of the research partnership will result in more clinical trial options for our patients and will lead to new and innovative therapies.

The five-year grant from the National Institutes of Health will create a Center for Clinical and Translational Science at UTHSC-Houston, the first such institution in Texas and only the third in the nation to receive this new type of grant. UTHSC-Houston was one of just 12 academic health centers nationally to earn the highly competitive grant. Other recipients included Duke University, Yale University and the Mayo Clinic College of Medicine.

It will fund a full range of projects and initiatives, including:

- Speeding up translational research – the process of developing new drugs and treatments, testing them on patients and providing the results to physicians
- Training medical students to become experts in translational research
- Assisting doctors who do not have academic credentials to participate in clinical trials
- Developing systems to improve sharing of information about current medical breakthroughs

Dr. Elias A. Zerhouni, director of NIH, said the institutions make up a new national consortium that will change the way clinical and translational research is conducted.

“The development of this consortium represents the first systematic change in our approach to clinical research in 50 years,” he explained.

“Working together, these sites will serve as discovery engines that will improve medical care by applying new scientific advances to real world practice. We expect to see new approaches reach underserved populations, local community organizations and health care providers, to ensure that medical advances are reaching the people who need them.”

THE DEVELOPMENT OF THIS CONSORTIUM REPRESENTS THE FIRST SYSTEMATIC CHANGE IN OUR APPROACH TO CLINICAL RESEARCH IN 50 YEARS.”

- DR. ELIAS A. ZERHOUNI

IRIS-UCRC INTEGRATION ADVANCES

Memorial Hermann-Texas Medical Center is moving toward an integration of UCRC research applications into the Web-based iRIS system.

The system allows researchers to submit their protocols electronically to the Institutional Review Board for review. Forms can be filled out and/or attached to each submission, and then be accepted and forwarded to the appropriate review board for assessment.

Reviewers can view protocol documents online, make recommendations and stipulations, record comments, and correspond with study staff electronically.

Currently, IRB and Memorial Hermann Hospital System research applications are available online. It is estimated that UCRC will be added by early 2007.

iRIS is a suite of applications designed to help create, manage and process research protocols. It is expected to move Memorial Hermann’s cumbersome, paper-based process to a more automated, more efficient, and more timely system.
Memorial Hermann-Texas Medical Center is undertaking a pilot study designed to streamline the review and approval of research projects by soliciting online, simultaneous comments from senior management.

The goal, said Administrative Director of Research Donna Grayson, is to make the process faster and more efficient by having the heads of applicable service lines look at research protocols earlier rather than later.

"We want to ask the people and departments involved in a protocol to comment at the same time," she explained. "If we can get the answers to key questions at the outset – questions about implementation and how the protocol will affect hospital operations – we can make better decisions."

Grayson said the online review will help address issues such as:

- Whether the hospital is adequately staffed to undertake the protocol
- The degree to which the research benefits both the hospital and patients
- What potential risks exist
- Where the study would take place in the event that multiple departments were involved
- Additional costs to the patients or hospital
- Whether the hospital has the physical capacity to conduct the protocol

"In the end, what we want to know is: Can this research take place at the hospital?" Grayson said. "Our hope is that the study will provide us the information we need and move us toward a more automated approach in the future."

Initially, five departments will participate in the study: investigational drug service pharmacy, radiology, laboratory, medical records, and heart and vascular nursing units.

Other departments will be added throughout the late summer and fall. Grayson said the goal is to have the online system in place hospital-wide by the end of the year.

The Center for Clinical Innovation and Research at Memorial Hermann-Texas Medical Center has been awarded a grant to help ensure that nurses, research nurses, and research coordinators receive the necessary training to conduct clinical trials.

The grant, from the Anne R. Wilford Endowment, will fund a project titled "A Nursing Education Program in Clinical Research: A Model of Safe and Ethical Research Practices for Clinicians."

Targeted at current and prospective research nurses in the Memorial Hermann Healthcare System and the University of Texas Health Sciences Center at Houston (UTHSC-H), the program will provide instruction in how to conduct medically innovative, high-quality clinical research that meets the demands of excellent patient care and safety.

In a letter accompanying the request, Dr. Cheryl Chanaud, executive director of the center, wrote, "We envision this program as integral to supporting the research enterprise across all facilities within the Memorial Hermann Healthcare System and in supporting our research partnership with UTHSC-H.

"(It) would provide an increased level of research professionalism within our organizations and facilitate a growing reputation in the Houston metropolitan area and with the industry and government sponsors of clinical trials."

The educational program will be the first of its kind in the Houston area. It consists of three live instructional sessions in the Texas Medical Center, as well as Web-based viewing that will be available to clinical nurses at other System locations.

Two seminars are planned for this year: January 2007 and June 2007.

The Anne R. Wilford Endowment Fund was established by Dan S. Wilford, former president and CEO of the Memorial Hermann Healthcare System, in memory of his late wife, who died in a 2003 automobile accident. It considers proposals in three areas: providing healthcare to indigent women and children; supporting school-based or community-based health clinics; and nursing education.

This is the first year that requests have been funded.

For more information, contact Zoe Fries at (713) 704-4386 or by e-mail at Zoe.Fries@memorialhermann.org.

"WE ENVISION THIS PROGRAM AS INTEGRAL TO SUPPORTING THE RESEARCH ENTERPRISE ACROSS ALL FACILITIES WITHIN THE MEMORIAL HERMANN HEALTHCARE SYSTEM AND IN SUPPORTING OUR RESEARCH PARTNERSHIP WITH UTHSC-H."

- DR. CHERYL M. CHANAUD
NEW RESEARCH AREA
“UNVEILED” AT OPEN HOUSE

More than 100 people attended the official “unveiling” of the Memorial Hermann Center for Clinical Innovation and Research and the University of Texas’ Clinical Research Center’s new location on the third floor of Robertson Pavilion in Memorial Hermann-Texas Medical Center. The expanded space provides a broad range of services and capabilities designed to enhance research activities as well as deliver an exceptional patient experience. The August open house included remarks from Juanita Romans, CEO of Memorial Hermann-Texas Medical Center, and James Willerson, M.D., president of the UT Health Science Center.

(LEFT TO RIGHT) BARRIE STRICKLAND, CFO; JUANITA ROMANS, CEO; DR. JERRY S. WOLINSKY, INTERIM DEAN, UTHSC; CHERYL M. CHANAUD, PHD, CCRP

UTHSC-HOUSTON PRESIDENT JAMES WILLERSON, M.D., SPEAKS AT THE OPEN HOUSE.