The institute is led by co-directors Alan R. Shuldiner, MD, and Stephen Davis, MBBS. Dr. Shuldiner is the John L. Whitemhurst Professor of Medicine, and Associate Dean for Personalized and Genomic Medicine. Dr. Davis is the Dr. Theodore E. Woodward Professor and Chair in the Department of Medicine. Both are experienced clinical and translational investigators whose combined expertise spans from basic discovery at the level of DNA to clinical research and community engagement. Both have a long track-record of continuous NIH funding and extensive experience in the administration of large multidisciplinary research programs and infrastructure grants, and in the mentoring and training of young investigators.

Under the CTSI, our basic science and clinical researchers will focus on chronic preventable diseases and diseases with high morbidity, high mortality, and high disability—areas where we can make an impact and transform lives for the better. These signature research areas include cancer, heart disease, infectious and inflammatory diseases, diabetes, schizophrenia and head injury. These illnesses have disproportionately higher morbidity and mortality in urban and rural underserved populations, and affect people across the entire lifespan.

Our CTSI partners will come together in an unprecedented and transformative way. Participating institutions include the professional schools of the University of Maryland, the University System of Maryland, the University of Maryland Medical System, the Baltimore VA Medical Center, the University of Maryland Medical System, and others. We will also partner with key institutions to strengthen our existing capabilities.

The CTSI will align with the newly emerging NIH NCATS and CTSA network, which embraces a reengineering of the clinical research enterprise. The institute will promote team science among investigators by providing an infrastructure to serve and support multidisciplinary research teams across the full spectrum of clinical and translational research. Such an infrastructure brings about efficiency and economies of scale, enhances the quality of research execution, and makes monitoring and compliance more effective.

In addition to conducting translational research, the institute will help advance interdisciplinary education of students in medicine, dentistry, nursing, pharmacy, social work, law, public health, biomedical engineering, and graduate studies. The CTSI will provide improved forums for setting priorities and enhancing communications with state and local agencies, community organizations and healthcare practitioners outside academia to help further provide evidence-based interventions designed to reduce healthcare disparities.

The CTSI will enhance our stature within the local community as well as our leadership in state and federal biomedical research and economic development arenas. It will give us a competitive edge in the pursuit of NIH funding, create jobs, promote the technology transfer, and advance public health opportunities. In the months and years ahead, we will be providing you with more information on how you can participate and help contribute to the CTSI’s mission to transform the research and clinical enterprise at the University of Maryland and across the nation.

In the relentless pursuit of excellence, I am

Sincerely yours,

E. Albert Reece, MD, PhD, MBA
Vice President for Medical Affairs, University of Maryland
John Z. and Akiko K. Bowers Distinguished Professor and
Dean, University of Maryland School of Medicine

Institute for Genome Sciences Director Claire Fraser-Liggett

ELECTED TO THE INSTITUTE OF MEDICINE

Claire Fraser-Liggett, PhD, professor, Department of Medicine and Microbiology & Immunology and director, Institute for Genome Sciences, has been elected a member of the Institute of Medicine of the National Academies. Dr. Fraser-Liggett is one of 65 new members and five foreign associates named to its membership this year.

Election to the IOM is considered one of the highest honors in the fields of health and medicine and recognizes individuals who have demonstrated outstanding professional achievement and commitment to service. New members are elected by current active members through a highly selective process that recognizes individuals who have made major contributions to the advancement of the medical sciences, health care and public health.

Dr. Fraser-Liggett is a world-renowned scientist, who through her pioneering research, her extensive peer-reviewed scientific publications, and her leadership of several prominent research institutions, has contributed significantly to the development of scientific progress of genomic medicine.

Over the past 16 years, Dr. Fraser-Liggett’s research team has applied large-scale DNA sequencing and analysis to the study of the microbial world and how it impacts human health. With the groundbreaking 1995 publication of the first complete genome sequence of a free-living organism, the bacterium, Haemophilus influenzae, she and her team launched the field of microbial genomics, creating a paradigm shift in the study of microorganisms, and laying the foundation for new approaches to personalized medicine. Today, she is one of the most highly cited investigators in the field of microbiology microbial genomics. The completion of more than 1,000 microbial genome sequences today is a direct result of her team’s pioneering work in the developing new experimental and computational approaches to analyzing large quantities of genetic information.

“It is a great pleasure to welcome Dr. Fraser-Liggett to the Institute of Medicine,” said Dean E. Albert Reece, MD, PhD, MBA. “This membership is recognition of Claire’s impressive body of research and her overall contributions to science and biomedicine, which are many. It’s also an affirmation of the growing recognition of the potential of genomics to improve human health. Since we launched the Institute for Genome Sciences here on our campus in 2007, it has had a positive impact on countless peoples’ lives worldwide.”

“It is a tremendous honor to be elected a member of The Institute of Medicine. I look forward to contributing to my new colleagues’ efforts to aid those in government and in the private sector in dealing with our most pressing health care issues,” said Dr. Fraser-Liggett. “IOM’s inclusion of genomic scientists demonstrates how integral this new interdisciplinary and innovative field has become to making breakthroughs in medical treatments and to developing new approaches to address the important biomedical challenges facing our nation.”
Young women with early-stage breast cancer have similar survival rates with breast-conservation therapy as mastectomy

New study by University of Maryland researchers analyzed data from nearly 15,000 patients

Young women with early-stage breast cancer have similar survival rates with a lumpectomy and radiation treatment, known as breast-conservation therapy, as with mastectomy, a new study conducted at the University of Maryland has found. The results of the analysis of nearly 15,000 patients listed in a nationwide cancer registry were presented at the 2011 Breast Cancer Symposium held in San Francisco.

Steven J. Feigenberg, MD, associate professor, Department of Radiation Oncology, says that mastectomies among young women have been on the rise, in part because of concerns regarding recurrence of their cancer. Dr. Feigenberg is also a radiation oncologist at the University of Maryland Marlene and Stewart Greenebaum Cancer Center.

“We believe these findings are very significant for young women with early-stage breast cancer who might choose to have a mastectomy in the hope of improving their outcome. This study confirms that breast-conservation therapy is a safe, effective treatment option and will not have a detrimental effect on survival,” Dr. Feigenberg, the study's senior author, said.

He says this is the largest study to date to compare survival in young women with early-stage breast cancer who had breast-conservation therapy vs. mastectomy. Women under 45 can have more aggressive tumors and are often at higher risk for having their cancer recur. Previous studies have suggested that young women have higher local recurrences of their cancer with breast-conservation therapy, but these studies did not demonstrate an effect on survival, Dr. Feigenberg stated.

Uusama Mahmood, MD, a lead author, said, “We looked at data from nearly 15,000 women in our retrospective analysis and saw no difference in survival between those who had breast-conservation therapy and those who had a mastectomy.”

Dr. Mahmood, a former resident in the Department of Radiation Oncology at the University of Maryland who is now at the University of Texas MD Anderson Cancer Center, will present the data at the Breast Cancer Symposium.

Researchers analyzed data from the SEER (Surveillance, Epidemiology and End Results) registry, which is maintained by the National Cancer Institute. They identified 14,764 women, age 20 to 39, who were diagnosed with early-stage breast cancer between 1992 and 2007. Forty-five percent of the women had breast-conservation surgery, and 55 percent had a mastectomy. Patients who received breast-conservation therapy were older and had smaller, lower-grade tumors and less lymph-node involvement. The median follow-up was nearly six years, although some patients were followed for 10 years, 15 years and beyond. All of the breast cancers were early-stage. Sixty-four percent of the patients were white.

To confirm the results of the study, the researchers did a “matched pair analysis, using a smaller group of 4,644 patients who had undergone breast-conservation therapy and mastectomy. Patients were matched for such factors as year of their diagnosis, age, grade, tumor size, number of positive lymph nodes, the number of nodes removed and their particular type of breast cancer, and still there was no difference in overall survival or survival specific to breast cancer. Similarly, a separate analysis was performed on the youngest group of patients, under age 33, again seeing no difference in outcomes.

The overall survival for those who had breast conservation therapy was 92.5 percent after five years, 83.5 percent after 10 years, and 77 percent after 15 years. That compares with
Whole-Parasite Malaria Vaccine Shows Promise

Vaccine is First of Its Kind to Earn FDA Approval to Test in Humans

FOR THE FIRST TIME, A MALARIA VACCINE
that uses the entire malaria parasite has proven safe and shown promise to produce a strong immune response in a clinical trial, according to a new study co-authored by researchers at the Center for Vaccine Development. The vaccine is unique in that it employs the entire malaria parasite, while most experimental malaria vaccines consist of just one or at most a few proteins found in the parasite.

Researchers found that the vaccine—the first whole parasite vaccine to be approved by the U.S. Food & Drug Administration for clinical trials—could provide unprecedented immune responses against malaria when administered intravenously. The study was published online in the journal Science in September.

“This is the first whole-organism malaria vaccine ever produced,” said Kirsten Lyke, MD, associate professor, Department of Medicine, and a search scientist at the Center for Vaccine Development. Dr. Lyke was one of three lead authors and two senior authors on the study, along with colleagues from the U.S. Military Malaria Vaccine Program at the Naval Medical Research Center, the Vaccine Research Center at the National Institutes of Health (NIH), and the Rockville-based biotechnology firm Sanaria, Inc., which helped produce and test the vaccine.

“No vaccine has completely protected against malaria in a challenge trial, in which vaccinated volunteers are subjected to the bite of an infected mosquito to measure their immunity,” said Dr. Lyke. “This vaccine showed strong promise. We hope that with further study it could help revolutionize the field and prevent death and ill health from malaria worldwide, and be used to eliminate malaria from certain areas.”

Though malaria has been largely eliminated in much of the developed world, it is still a widespread threat in warm, tropical areas where infected mosquitoes thrive, such as Africa. Malaria, caused by a parasite transmitted through the bite of an infected mosquito, kills nearly one million people and infects 300 million annually worldwide. The condition can be treated with anti-parasite drugs, but can have fatal consequences for vulnerable patients who have no immunity to the disease. Children under the age of five succumb at high rates to the neurological and cardiac effects of malaria, particularly in Africa.

Researchers found that the vaccine produced a partial protective response in the 80 volunteers who were immunized subcutaneously, or under the skin, by traditional needle and syringe in the trial at the Center for Vaccine Development in Baltimore. However, this response was significantly less than the 80 to 90 percent protective immunity the research team is intent on achieving.

Researchers suspected that administering the vaccine more directly into the bloodstream, accelerating its path to the liver, might produce an even stronger response. Further study conducted by collaborating authors from the Vaccine Research Center at the NIH found that administering the vaccine intravenously produced a very high level of immune response in animal subjects.

“Our hope is that we can optimize the delivery of this vaccine to prevent and eliminate malaria on a global level,” said Dr. Lyke. She and her colleagues are already at work designing new studies to find the best way to administer the vaccine.

Scientists consider a whole-parasite vaccine to be the “holy grail” of malaria vaccine research. Such a vaccine is believed to be more capable of broadly protecting people against the scores of varying strains of malaria. Historically, vaccinators have been confronted with the fact that malaria parasites are highly variant malaria parasites are difficult to prevent with single-strain, single-protein vaccines. “That will be the real test—does this vaccine have the ability to immunize humans against malaria. In fact, previous trials pioneered at the University of Maryland School of Medicine and the U.S. Navy 40 years ago showed that 90 percent of humans bitten by at least 2000 infected and malaria-car- rying mosquitoes did not contract malaria from the bites of ordinary malaria-infected mosquitoes. However, the bite of a mosquito—essentially using a mosquito as a syringe and needle—is not a practical method of administering a vaccine to large groups of people. Sanaria’s large-scale production and cryopreservation process creates the potential for the vaccine to be administered globally.

The study included 98 adult volunteers, 18 of whom served as control vol- unteers. As a Phase I trial, the study’s focus was to establish that the vaccine was safe and well tolerated. The results have guided the design of the next study, a Phase II clinical trial in which scientists will administer the vaccine intravenously to human volunteers and measure immunity to determine the effectiveness of Sanaria’s vaccine. Scientists have traditionally regarded intravenous delivery as an impractical strategy for large-scale global immunization, but Dr. Lyke said the researchers will evaluate its potential in future studies. Other possibilities for administering the vaccine might include novel microneedle injection devices. If these studies continue to show promise, the next step would be to test the whole parasite vaccine’s ability to prevent malaria in people naturally exposed to malaria.

“We would love to test this vaccine in Mali,” said Dr. Plowe, who has led several malaria vaccine trials in Mali, West Africa. There, his team found that highly variant malaria parasites are different from those found in the United States with single-strain, single-protein vaccines. “That will be the real test—does this vaccine have enough immunological firepower to protect against all the different strains circulating in the field, not just the strain the vaccine is based upon? If the vaccine doesn’t work, I don’t know what will—this is the best chance we’ve got.”

91.9 percent, 83.6 percent and 79.1 percent, respectively, for those who had mastectomies. In addition, the breast cancer-specific survival rates were simi- lar between the two groups.

The study’s authors include members of the multidisciplinary breast cancer team at the University of Maryland Marlene and Stewart Greenebaum Can- cer Center. In addition to Dr. Feigenberg, co-authors include Katherine Tkac- zuk, MD, professor, Department of Medicine, and a medical oncologist who heads the Breast Evaluation and Treatment Program; Susan Ksmedel, MD, assistant professor, Department of Surgery, and a surgical oncologist; and two medical oncologists, Saranya Chumti, MD, assistant professor, Department of Medicine, and Ting Tao, MD, assistant professor, Department of Medicine.

The 2011 Breast Cancer Symposium is a three-day multidisciplinary sym- posium, sponsored by the american Society of Clinical Oncology, American Society of Breast Disease, the American Society of Breast Surgeons, the American Society for Radiation Oncology, the National Consortium of Breast Centers and the Society of Surgical Oncology.
and applied for several more. Led by Dr. Strome, Gliknik is developing novel biotechnology drugs for patients with cancer and autoimmune/inflammatory diseases. Dr. Strome praises the state biotech tax credit and the Maryland Industrial Partnerships program in College Park for contributing to Gliknik’s success. In addition, “Jim Hughes and the entire staff at the Office of Research and Development have really done a terrific job in guiding me through this process,” he commented, “and the offices of President Perman and Dean Reece have been incredibly supportive.”

Meeting the definition of a true entrepreneur, Dr. Strome sees this award as fuel for further translational discoveries. “It is my goal for our lab and our department to remain active in discovering new biologic pathways and in working collaboratively with industry to create new therapeutic interventions to help patients across a wide range of disorders,” he said.

Call for Photos!

Send us photos of your favorite activity for the next Call for Photos. To participate, submit your photograph(s) to photos@som.umaryland.edu by December 1, 2011.

E. Albert Reece, MD, PhD, MBA
Vice President for Medical Affairs, University of Maryland
Johns Hopkins Queen’s Distinguished Professor and Dean, University of Maryland School of Medicine

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