The Joseph Stokes Jr. Research Institute
Research Annual Report

hope  {hōp}
n. 1. the feeling that what is wanted can be; v. 1. to wish for something with expectation of its fulfillment; 2. to believe, desire, rely or trust

The Children’s Hospital of Philadelphia®
Hope lives here.

2007
Mission
We advance the health of children by turning scientific discovery into medical innovation.

“Where the world ceases to be the scene of our personal hopes and wishes, where we face it as free beings admiring, asking and observing, there we enter the realm of Art and Science.”

Vision
We will be the preeminent institution in the world dedicated to translational research for children.
greet·ings

n. (greet·ings)
1. a cordial and often conventional gesture or expression used when welcoming, meeting or addressing somebody;
2. an expression of friendly or respectful regard
We are again proud to bring you the annual report for the Joseph Stokes Jr. Research Institute at The Children’s Hospital of Philadelphia.

As the Hospital continues its unprecedented growth, the number and breadth of the research programs at the Stokes Institute grow in parallel. With literally hundreds and hundreds of cutting-edge research studies at our disposal, it was difficult to choose just a handful to feature in the report. This dilemma led us to consider how we define “success.”

Success for us is not simply encapsulated by quantitative factors like funding levels, amount of space, or the number of investigators and research staff who contribute their intelligence and talents. While such figures are no doubt important in our day-to-day business, the numbers fail to tell the really important story.

We believe our success is due in large part to qualitative traits like commitment, discovery and innovation. These are the traits we value as we continue to strive for cures for pediatric diseases that afflict our patients and their families. And when this filter is applied a theme for this year’s report emerges — our research saves lives. Every day of every year.

This is just the latest chapter on how the Stokes Institute continues as the world leader in pediatric healthcare research. We hope you enjoy our stories, and we will bring you many more in the coming years.

Philip R. Johnson Jr., M.D.  
Chief Scientific Officer and Senior Vice President  
Director, Joseph Stokes Jr. Research Institute

Tristram C. Colket Jr.  
Chair, Joseph Stokes Jr. Research Institute Board Committee

Steven M. Altschuler, M.D.  
President and Chief Executive Officer
Pursuing Research Preeminence
A diagnosis of cancer, especially in a child, brings with it fear — and a lot of questions.

"Will my child survive? Will the cancer come back? What are the treatment options and side effects? What will my child’s quality of life be? How does our family cope?"

A few short decades ago cancer in children was usually fatal. Families were understandably devastated. Today, a cancer diagnosis is initially no less devastating, but with it comes greater hope for successful treatment. Nearly three out of four children with cancer today are cured, and investigators have more precise answers to some of parents’ most difficult questions.

Stokes investigators have been at the forefront of pediatric cancer research for decades, and today Children’s Hospital is recognized as a world leader in research and treatment of childhood cancers, most notably neuroblastoma, leukemias and brain tumors.

The Hospital’s reputation in oncology was bolstered this year by the launch of the Center for Childhood Cancer Research. By translating the latest in cutting-edge research into innovative clinical trials, the center aims to increase the cure rate in children with cancer using more precise, and therefore less toxic, therapies.

The collaborative and “bench to bedside” nature of research at the Stokes Institute, in addition to the dedication of the Institute’s talented investigators, increases the odds that one day all children battling cancer will be cured.

The following pages describe some of the most innovative oncology research programs underway by Stokes investigators and their pursuit of new therapeutic strategies.
dedication

n. [ded-ka-sbon]
1. selfless devotion;
2. an expression of faithfulness, loyalty
Although the survival rate for children with leukemia has increased over the past 30 years, infants battling this blood cancer face increased challenges. Leukemia in infants is often resistant to available therapies and these babies are especially vulnerable to treatment side effects.

Children’s Hospital is leading an effort to harness the understanding of genes and molecular pathways toward the development of highly specific drugs designed to kill leukemia cells in infants while causing few side effects.

Carolyn Felix, M.D., leads the five-year, $6.25 million Specialized Center of Research (SCOR) in Targeted Therapies for Infant Leukemias that enables investigators to perform rigorous preclinical and clinical studies of molecularly targeted therapies and evaluate their potential use.

Dr. Felix pioneered new technologies to characterize the many chromosomal translocations in a gene critical for blood cell development, MLL (Mixed Lineage Leukemia), that causes the poor prognosis in infants with leukemia. The translocations happen when the MLL gene breaks and recombines with one of many partner genes. The abnormal protein products of translocated MLL genes signal entire networks of abnormal expression of other leukemia-associated genes. The protein products of these genes and other interacting factors may be targets for new therapeutic agents.

Each of the four projects supported by the multicenter SCOR focuses on a particular aspect of infant leukemia that together may help solve the puzzle for this refractory disease.

As the avenue to new treatments, the SCOR investigators are using microarray analyses to identify the abnormal gene expression that occurs as a consequence of MLL translocations. These studies form the basis for developing novel drugs that either promote leukemia cell death or interfere with the propensity of the leukemia cell population to proliferate and expand. Because leukemia stem cells are critical for producing the leukemia cell population, other research in the SCOR is directed at characterizing and targeting these stem cells with MLL translocations to obtain lasting cures.

Dr. Felix and her colleagues collaborate with the Children’s Oncology Group (COG), the national cooperative group for pediatric cancer research and treatment. Working with COG, the SCOR team will begin testing the first molecularly targeted agent ever used for infants with leukemia. Because even the largest medical center has a relatively small number of patients with infant leukemia, collaborating with COG allows investigators to conduct clinical trials and capture information about the majority of infants throughout North America with acute leukemia.

“The SCOR grant brings together investigators from around the United States and harnesses our efforts to build bridges between basic science and bedside treatments and have the utmost impact for infants with this dread disease,” says Dr. Felix. “The award creates a unique opportunity to produce advances against a very challenging form of leukemia.”
<Increasing the Success of Stem Cell Transplantation>

The cure rates for acute lymphoblastic leukemia (ALL), the most common pediatric cancer, have increased dramatically over the last several decades thanks to a better understanding of how the disease works and the development of new treatments and other therapeutic strategies. There has also been substantial progress in identifying children with lower-risk disease who need less therapy, sparing those children long-term treatment side effects.

Despite these successes, however, many children initially treated for ALL will experience a relapse, which brings with it an extremely poor prognosis for further successful treatment. Even with the current good success rates, relapsed ALL is the fifth most common pediatric cancer.

The best available treatment for children with relapsed ALL is hematopoietic, or blood-forming, stem-cell transplantation (SCT). However, SCT is successful for less than half of all ALL patients. Stephan Grupp, M.D., Ph.D., is spearheading the Children’s Hospital efforts aimed at increasing the cure rates of relapsed ALL through the use of stem cells in cancer therapy.

An international leader in pediatric cancer therapeutics and stem-cell transplantation, Dr. Grupp serves as the chair of Stem Cell Transplantation for COG and director of Stem Cell Biology at Children’s Hospital, where he oversees research into cellular and immune-based therapies for children with intractable cancers.

Dr. Grupp’s laboratory studies antibody-producing B cells that, when growing abnormally, may lead to ALL. He identified a pathway called mTOR that is essential in normal developing B-cells. His work has shown that abnormalities in the pathway are potential treatment targets in ALL as well as other types of cancer.

One focus of Dr. Grupp’s bench-to-bedside research is the mTOR inhibitor rapamycin, which has shown preclinical activity in ALL. His work in the laboratory led to a multi-institutional pilot trial, which in turn allowed the development of a nationwide phase III clinical trial testing rapamycin to prevent relapse after stem-cell transplantation for ALL. This four-year study is now a centerpiece of the COG stem-cell transplant research agenda.

At the same time, Dr. Grupp received a $1.5 million grant from the National Institute of Health (NIH) to support further scientific studies based on the national clinical trial, with Children’s Hospital as the lead institution.

“We have really taken this concept full circle,” says Dr. Grupp. “We did the basic science research to demonstrate that this pathway might be important in ALL, identified a drug that could hit this potential target, tested it in early-phase clinical trials, brought the concept forward to a phase III trial, and now have additional funding to do more discovery research based on the patient specimens that come from children in the trial.”

Among Dr. Grupp’s clinical research interests is a tandem, or two-cycle, stem-cell transplant program that has led to an improvement in event-free survival for children with neuroblastoma, a disease with less than 15 percent long-term survival with standard chemotherapy and approximately 35 to 40 percent survival with the current standard of care — chemotherapy plus single stem cell transplant. This research program has led to another COG phase III trial testing the tandem SCT concept.

In addition, the tandem SCT approach has formed the core of an innovative cell therapy study at Children’s Hospital using costimulated T-cell infusion to recover the immune system immediately after SCT, to allow for delivery of a cancer vaccine when the patient’s disease burden is the lowest and the potential for an immune-based treatment the highest.

“What we are aiming for in both of these translational research programs is to change the standard of care in two very difficult childhood cancers — relapsed ALL and neuroblastoma,” says Dr. Grupp.
These findings have direct translational significance in leukemia, and offer us hope that we can improve treatment success in relapsed ALL, says Dr. Grupp.

commitment

n. (kəm-mît-mənt)
1. pledge or promise; obligation;
2. engagement, involvement
**dis·cov·ery**

n. (dis·kuv·er·y)
1. the observation, identification, description, experimental investigation, and theoretical explanation of phenomena;
2. acts in which something is found and given a productive insight
Despite the improved cure rates for pediatric cancer, one in four children still die from their disease, and the short- and long-term side effects of current therapy can be substantial. Treatment approaches over the past 15 years have focused primarily on methods to increase the intensity of treatment. Improvements in cure rates, however, have not paralleled this increase in treatment intensity. Future improvement in cure rates, and more tolerable treatment regimens, must emerge from the identification of new anticancer drugs.

The evolution in our understanding of the molecular basis of cancer has provided a foundation for the development of more effective and less toxic treatments. Recently developed molecular-targeted drugs for use in adults may have a role in pediatric treatments as well, and Children’s Hospital investigators are studying these drugs and other novel therapeutic approaches.

“Our advances in the treatment of children with cancer over the past 40 years have indeed been remarkable, but there are still too many children who do not benefit from existing therapies, and those who do survive often pay a high price for cure,” says Peter Adamson, M.D., who investigates experimental therapeutics at Children’s Hospital and serves as the director of Clinical and Translational Research at the Stokes Institute.

Dr. Adamson also leads the National Cancer Institute (NCI)-funded, 21-university COG Phase I and Pilot Consortium. The consortium does the initial evaluation of new anticancer drugs in children. Since its inception in 2001, the consortium has conducted more than 25 phase I studies. With leadership based at Children’s Hospital, this collaborative program is the largest venue for pediatric cancer drug development in the world, overseeing an extensive portfolio of novel anticancer drugs.

Under Dr. Adamson’s leadership, the consortium works not only with the NCI, but also with major pharmaceutical companies worldwide to plan pediatric cancer drug development. Although only children with relapsed or refractory cancers participate in these types of studies, the knowledge gained is the cornerstone of new treatments for future generations of children affected by cancer.

Children’s Hospital investigators also participate in two other NCI-funded groups focused on pediatric cancer. Peter Phillips, M.D., leads the Children’s Hospital site for the Pediatric Brain Tumor Consortium (PBTC), one of 13 sites conducting phase I and II clinical trials of new drugs, agents and delivery techniques and strategies in children with brain tumors. And John Maris, M.D., the director of the Center for Childhood Cancer Research, leads the Children’s Hospital site for the New Approaches to Neuroblastoma Therapy (NANT) consortium. Composed of 13 universities and pediatric hospitals, NANT tests promising new approaches for treating children with high-risk and relapsed neuroblastoma, a peripheral nervous-system tumor. Promising drugs against pediatric cancers are then tested on a larger scale across the country.
Dr. Maris is among the world leaders in neuroblastoma research and treatment. His lab houses tissue samples from more than 5,000 patients — the world’s largest sample collection for the disease.

Along with his colleagues, Dr. Maris is looking for new approaches to treatments for children whose neuroblastoma has relapsed in an aggressive form, a particularly challenging set of patients. One technique used and studied at Children’s Hospital employs radioactive isotopes that zero in on neuroblastoma cells to selectively kill those cells with radiation. Other tools include biological molecules that hone in on cancer cells, angiogenesis inhibitors that cut off a tumor’s blood supply, and tyrosine kinase inhibitors that interrupt a critical step in the tumor’s growth process.

Children’s Hospital investigators evaluate other potential experimental therapeutics by leading or participating in all major pediatric cancer studies funded by the NCI.

As a result of its multi-pronged approach to finding the best treatment for children, the Hospital has one of the largest portfolios of pediatric anticancer drugs of any center in the nation.

“These early phase studies allow us to begin the critical evaluation of promising new therapies for children. Results help guide which therapies should then be further evaluated nationwide,” says Dr. Adamson. “Importantly, these studies also can provide hope to children whose disease has recurred and for whom no known curative pathway exists.”
n. [kyoor]
1. a remedy; recovery from disease;
2. a method or course of medical treatment used to restore health
Progress Notes
Groundbreaking research, innovative programs, interdisciplinary collaborations and a direct link from the bench to the bedside are the hallmark of research at Children’s Hospital. This world-renowned research program receives the third-largest portion of NIH funding to pediatric hospitals, an impressive 256 awards during fiscal year 2007. Using this support and other donations, Hospital investigators have published more than 450 publications during the year, including many in high-impact journals including the New England Journal of Medicine, the Journal of the American Medical Association, Science, Pediatrics, Lancet, Human Mutation, Genome Research, Developmental Cell, Nature Immunology, the Journal of Clinical Oncology, and the American Journal of Human Genetics.

These awards and publications — a sliver of the outstanding research program at the Stokes Institute — reflect the commitment to excellence in basic, clinical and translational research conducted at Children’s Hospital.
<Clinical and Translational Science>

Children's Hospital and the University of Pennsylvania successfully began a new collaboration, becoming a NIH-funded new Clinical and Translational Science Awards (CTSA) center, part of a nationwide effort to transform translational biomedical research. Under the CTSA, the NIH awarded the University of Pennsylvania School of Medicine and Children's Hospital a $68 million grant over the next five years. Additional institutional commitments from Penn and Children's Hospital have resulted in close to $100 million dedicated to targeting clinical and translational research.

In addition to the School of Medicine and Children's Hospital, The Wistar Institute, the University of the Sciences in Philadelphia and several other Penn schools comprised the collaborative effort, successfully competing and becoming a member of the first group of 12 academic health centers throughout the country to receive the CTSA awards. Children's Hospital is one of only two pediatric hospitals to receive initial funding through the CTSA.

This collaboration will develop a better infrastructure for the conduct of clinical and translational research, spearhead new designs for clinical trials, improve research bioinformatics, expand outreach to minority and medically underserved communities, and forge new partnerships with private and public healthcare organizations. When fully implemented in 2012, approximately 60 institutions will be linked together to energize the discipline of clinical and translational science.

<Research in the Primary Care Setting>

The Pediatric Research Consortium (PeRC) at Children's Hospital uses its expanding organizational and technological infrastructure to support the largest pediatric integrated delivery system in the country. PeRC aims to improve children's health by connecting clinicians and practices with investigators who are examining clinical questions that, when answered through rigorous scientific methods, will improve the delivery of primary care to children and families.

PeRC provides the infrastructure to perform high-quality research based on the clinical needs of the primary care practices within the Children's Hospital network, including four primary care centers, the faculty practice, and more than 30 Kids First practices. These efforts were recently bolstered by the Agency for Healthcare Research and Quality (AHRQ), which designated PeRC as a "Master Contractor," one of only 10 practice-based research networks (PBRNs) receiving this distinction, and the only pediatric PBRN awarded this status.

Under the three-year contract, Louis Bell, M.D., as medical director, and Marguerite Swietlik, M.S.N., C.R.N.P., as network director, respond to AHRQ requests for task orders ranging from $100,000 to $300,000 each. As an AHRQ contract recipient, Children's Hospital is uniquely positioned to bid on task orders to address pressing primary care questions, evaluate healthcare delivery strategies, or assess a technology, product, or tool proposed for use in the healthcare system.
<Language Impairment in Autism>

Autism and the autism spectrum disorders affect approximately one in 150 children. These disorders are often associated with language-impairment (LI), defined by reduced cognitive capacity for speech and nonverbal communication. Real-time visualization of electrical brain activity using magnetoencephalography (MEG) could provide a novel diagnostic tool for LI and greatly enhance the understanding of language cognition and physiology. This understanding may also provide insight into the similarities and differences between the brains of children with autism spectrum disorders and other neurodevelopmental disorders.

The NIH awarded Timothy P.L. Roberts, Ph.D., Department of Radiology, with a $1.25 million, five-year award to evaluate LI in the pediatric population. As part of this award, Dr. Roberts hopes to identify and differentiate between the electrical “signatures” that underlie language impairment in the brains of autistic children and unaffected children. MEG provides a unique technology to track these signals within the brain, with real-time speed.

In Dr. Roberts’ clinical studies, participants will be exposed to various auditory or speech stimuli while their brain function is monitored. Changes in the electrical brain signatures in response to these stimuli will allow for in-depth analyses of brain activity between groups. Dr. Roberts’ research will also examine the correlation between neuronal white matter maturation and electrical brain signatures in the context of childhood development. Deficient white matter development could be part of the mechanism of reduced or delayed brain activity and the onset of LI.

<Other Notable Grant Awards>

Peter White, Ph.D., Division of Oncology, “Genome Copy Number Variation Analytics,” $3,315,523 (Pennsylvania Department of Health)

Douglas Coulter, Ph.D., Division of Neurology, “Epileptogenesis: Causes, Consequences and Treatment,” $1,261,077 (National Institutes of Health)

Steven Douglas, M.D., Division of Allergy and Immunology, “Philadelphia IMPAACT Clinical Trials Unit,” $901,130 (National Institutes of Health)

Jeffrey Silber, M.D., Ph.D., Division of Oncology, “Obesity and Surgical Outcomes,” $663,047 (National Institutes of Health)

Nathan Blum, M.D., Division of Child Development, Rehabilitation and Metabolic Disease, “UAP Leadership Education in Neurodevelopmental and Related Disabilities,” $643,609 (Maternal and Child Health Bureau)

Fraser Wright, Ph.D., Division of Hematology, “NHLBI Gene Therapy Resource Program (GTRP) - Adeno-Associated Virus (AAV) Vector Production Core Laboratory,” $630,516 (National Institutes of Health)

Mary Leonard, M.D., M.S.C.E., Division of Nephrology, “Bone Health in Pediatric Crohn’s Disease: A Low Magnitude Mechanical Stimulus Trial,” $566,758 (National Institutes of Health)

Stephen Leff, Ph.D., Division of Child Development, Rehabilitation and Metabolic Disease, “Determining the Effectiveness of a Relational Aggression Intervention for Urban African American Girls,” $517,150 (National Institutes of Health)

Rebecca Ichord, M.D., Division of Neurology, “Validation of the NIH Stroke Scale in Children,” $500,448 (National Institutes of Health)
Lung Disease in Premature Infants

Delivering nitric oxide to the lungs of premature, very-low-birth-weight infants beginning in their second week of life improves their chances of surviving without chronic lung disease, or bronchopulmonary dysplasia, according to a multicenter study of nearly 600 babies led by Roberta A. Ballard, M.D., Division of Neonatology. The study was published in the New England Journal of Medicine.

Investigators found the rate of survival when infants were about 10 weeks old was 7.1 percent higher in treated infants compared to the control group. Infants who received treatment beginning between 7 and 14 days after birth had a more pronounced response; the rate of survival without chronic lung disease was 21.3 percent higher in infants who received nitric oxide compared with infants who did not receive this treatment.

Lung disease was also less severe in treated infants; they had shorter hospitalizations and less need for mechanical ventilation or oxygen therapy than infants in the control group. In addition to the clinical benefits, the investigators found no adverse effects from the nitric oxide up to 44 weeks of age and improved respiratory outcome at 1 year of age. The study team expects to provide definitive recommendations for clinical use of nitric oxide after it analyzes follow-up studies of the children’s neurodevelopmental status at 2 years of age.

<Genetic Breakthrough in Alagille Syndrome>

In a finding that may have broader implications for understanding kidney disorders, investigators led by Nancy B. Spinner, Ph.D., Division of Human Genetics and Molecular Biology, and David A. Piccoli, M.D., chief of the Division of Gastroenterology, Hepatology and Nutrition, found that mutations in the NOTCH2 gene were linked to kidney abnormalities in patients with Alagille syndrome and their families. This is the first study to report that mutations in the NOTCH2 gene cause human disease.

A complex disorder affecting the liver, heart, eyes, face and skeleton, Alagille syndrome occurs in one in 20,000 individuals. Dr. Spinner’s team previously found that 94 percent of patients diagnosed with Alagille syndrome had mutations in the JAG1 gene. In the current study, published in the American Journal of Human Genetics, they analyzed 11 patients with Alagille syndrome who did not have the JAG1 mutation, and found that two of them had mutations in NOTCH2. Furthermore, the patients had three family members who were mildly affected and had the same mutation. All five individuals had kidney disease.

While Alagille syndrome is relatively rare, diseases of the organs affected in Alagille syndrome are not rare, and these findings suggest that genes on the Notch signaling pathway, which involves both NOTCH2 and JAG1, may have a broader role in kidney disorders. Dr. Spinner is planning further studies to better characterize the role of NOTCH2 mutations and the Notch signaling pathway in the wider population of patients with kidney disorders.

<Teen Driving>

Motor vehicle crashes are the leading cause of death among children and teens in the U.S. Children’s Hospital and State Farm Insurance Companies have been working together for a decade to address the urgent need to advance science to reduce death and injury to children in car crashes through Partners for Child Passenger Safety, the world’s largest study on the topic. Three years ago, the award-winning academic-industry research alliance extended its focus from child safety seats to the driver’s seat — building a new focus on teen drivers.

In a landmark study, the National Young Driver Survey, investigators led by Flaura Winston, M.D., Ph.D., co-scientific director of the Hospital’s Center for Injury Research and Prevention, surveyed 5,665 ninth, 10th and 11th grade students from 68 randomly selected schools across the country. This study is the most comprehensive current description of youth perceptions of teen driving, representing all 10.6 million public high school students in the U.S. They found that many teens are driving under extremely dangerous conditions — fatigue, distractions, and speeding — and many are still not wearing seatbelts.

This valuable information sheds light on appropriate targets for teen-focused intervention that the research team will develop, test and disseminate.

Parents will be another important audience, as teens revealed the importance of parents and community in influencing their driving behaviors.

The National Young Driver Survey demonstrated that teens understand the messages about the dangers of drinking and driving but do not comprehend as clearly the risks involved with other driving distractions and fatigued driving. It takes only three seconds of distraction for a car ride to become a deadly crash, but teens frequently see other teens driving with passengers, talking on cell phones, text messaging, playing loud music and having heightened emotions.

Many researchers have proposed that adult stem cells in the pancreas are capable of developing into functional insulin-producing cells, called beta cells, which maintain proper insulin generation and prevent diabetes. However, a surprising discovery led by Jake Kushner, M.D., Division of Endocrinology, suggests that adult stem cells do not maintain the beta cell population of the pancreas. Instead, the beta cells themselves divide slowly to replenish their own population and maintain insulin generation.

 Unexpectedly, the researchers also discovered that the beta cells undergo a prolonged waiting period between divisions. This delay, which they call a replication refractory period, had never been observed in mammalian development and hints at a novel mechanism of growth control in beta cells. These findings, published in Developmental Cell, do not have immediate implications for diabetes treatment. Rather, they advance the understanding of insulin biology and could form a foundation for future therapies.

This research also has implications for beta cell regeneration, a controversial area of research that aims to stimulate the proliferation of the small amounts of beta cells remaining in patients with type 1 diabetes. It may someday be possible to regenerate enough cells to produce healthy amounts of insulin. If these findings open up a new avenue of investigation into how insulin-producing cells are propagated, diabetes researchers may be a step closer to manipulating the process to benefit patients.

In the largest-ever study of adult survivors of childhood cancer, investigators led by Anna Meadows, M.D., Division of Oncology, found survivors to be more than three times as likely to have a chronic health condition and more than eight times as likely to have a severe or life-threatening condition when compared with their siblings. Published in the New England Journal of Medicine, this study highlights the importance of continued medical surveillance of adult survivors of childhood cancer.

The incidence of these chronic conditions increased over time and did not appear to level off over the time span studied. The long-term survivors were particularly vulnerable to second cancers, heart conditions, kidney disease, severe musculoskeletal problems and endocrine abnormalities such as thyroid disease, osteoporosis and sterility. Female survivors were at higher risk for chronic illnesses than male survivors.

One implication of the current study is the need for continued medical surveillance of adult survivors of childhood cancer. Fewer than 20 percent of these patients are followed by an oncologist or at a cancer center, but they clearly have special medical needs and higher risks. The study's investigators suggest that because of the influence of studies on treatment effects, and based on clinical trials in pediatric oncology that have led to improved treatments over the years, children diagnosed with cancer since 1987 will have fewer chronic problems as survivors than the cohort analyzed in the current study.

Other Notable Publications

Childhood Obesity

When combined with behavior therapy, the weight loss medication sibutramine—sold under the brand name Meridia®—may help obese adolescents lose weight, according to the first large multicenter trial of the medication for obese adolescents, led by Robert Berkowitz, M.D., Department of Child and Adolescent Psychiatry. Although further investigations are needed to analyze long-term outcomes and risks, this finding, published in Annals of Internal Medicine, may be promising for obese adolescents for whom behavioral therapies alone are not successful.


![Graph showing mean change in BMI, kg/m² over visits](image)
Cancer

In a study that reinforces previous findings, Greta Burin, Ph.D., Division of Oncology, found that women who take multivitamins early in pregnancy may reduce the risk that their child will develop some types of brain tumors. These results, published in Cancer Epidemiology Biomarkers & Prevention, in conjunction with the proven benefits of multivitamins in preventing neural tube defects, support the recommendation that all women of reproductive age take multivitamins even if they are not trying to get pregnant.


Adda G, Grimberg M, Division of Endocrinology, found that the tumor suppressor p53 increases production of a protein that binds to one of the principal regulators of body growth during childhood, making the growth factor less available to act on the body’s tissues. This study, published in Cancer Biology & Therapy, shows that the interactions among pathways affecting growth are more complex than previously appreciated, and may have implications for anticancer treatments as well as growth-promoting therapies.

**Influenza**

Ron Keren, M.D., M.P.H., Division of General Pediatrics, found that hospitalizing children for influenza may cost as much as three or four times the previously accepted estimates, suggesting that annual influenza vaccinations, especially those with certain high-risk conditions, may be more cost effective than originally thought.

The results, published in Pediatrics, strengthen the economic justification for broadly vaccinating children against flu and reinforce the decision by the American Committee on Immunization Practices to extend the ages and chronic conditions that warrant annual flu vaccination.

**Brain Injury**

Investigators led by Akiva Cohen, Ph.D., Division of Neurology, were the first to show that traumatic brain injury reduces the level of a protein that helps keep brain activity in balance. Published in Neurobiology of Disease, this finding may provide a scientific basis for eventual treatment of the seizures and memory defects associated with traumatic brain injury.

End-of-Life Care

Nurses with higher levels of hopefulness are more confident and competent in their ability to care for dying children and their families, and palliative care education helps nurses to more comfortably provide palliative care and talk about death and dying with parents and families, according to a study led by Chris Feudtner, M.D., Ph.D., M.P.H., and Gina Santucci, M.S.N., Division of General Pediatrics. Published in Pediatrics, this study may help educators develop programs to help nurses and other healthcare providers to address difficult situations.


Foster Care

David M. Rubin, M.D., M.S.C.E., Division of General Pediatrics, demonstrated that children in foster care have frequent placement changes that are unrelated to their behavioral problems. Those raised in stable home environments also displayed fewer behavioral problems than those with unstable, transient living conditions. These results, published in Pediatrics, call for greater attention to our foster care system, which may not be stabilizing children in permanent or adoptive homes as well as it could.

Genetics

Ian D. Krantz, M.D., and Matthew Deardorff, M.D., Ph.D., Division of Human Genetics and Molecular Biology, provided insight into the genetic basis of Cornelia de Lange syndrome in a publication in the American Journal of Human Genetics. The identification of two chromosome-stabilizing genes that when mutated lead to variable, mild symptoms of the syndrome may underscore a broader biological pathway required for the development of mental retardation and autistic disorders.


Hyperinsulinism

Innovative research conducted by Olga Hardy, M.D., Division of Endocrinology, utilized a novel positron-emission tomography (PET) scanning technique to visualize focal clusters of abnormal pancreatic insulin-secreting cells in patients who were diagnosed with congenital hyperinsulinism. The results, published in the Journal of Pediatrics, show that this accurate, non-invasive methodology allows physicians to pinpoint and remove the focal cluster of diseased cells, and have the potential to revolutionize the treatment of this rare, but serious disorder.

Lifestyle

Nicolas Stettler, M.D., M.S.C.E., Division of Gastroenterology, Hepatology and Nutrition, and Takehiro Sugiyama, a medical student at the University of Tokyo, Japan, published the first study to detail a direct connection between sedentary lifestyles and high blood pressure in adolescents independent of their body mass indexes. This study, published in the Journal of Adolescent Health, suggests that encouraging adolescent children to reduce their sedentary activities may function to reduce their blood pressure and thereby reduce their risk of cardiovascular disease and stroke in adulthood.


Medication Use

A retrospective study performed by Samir Shah, M.D., Division of Infectious Diseases, and published in the Archives of Pediatric and Adolescent Medicine, analyzed the medical histories of more than 350,000 pediatric patients to determine how often adult-approved medications without indications for pediatric use are administered to children in a hospital setting. Strikingly, 4 out of 5 hospitalized children receive medicines that have not been evaluated for efficacy and safety in the pediatric population, demonstrating the dire need for controlled clinical evaluations of medications in children.

Epilepsy

Groundbreaking research performed by Amy R. Brooks-Kayal, M.D., Division of Neurology, utilized gene therapy in the brain to enhance inhibitory neurotransmitter receptor expression and inhibit abnormal brain activity in injury-induced epilepsy in a model of the disorder. This novel approach, published in the Journal of Neuroscience, marks the first time that a post-injury treatment has been successful in curbing the onset of epileptic seizures.

Increasing α1 Protects Against Epilepsy after Brain Insult

Endowed Chairs
Stokes investigators work tirelessly to make scientific breakthroughs, deepening the collective scientific knowledge to cure pediatric diseases and further advance the health of children worldwide.

Critical to their efforts are internal and external support for their research programs. It is through such support that investigators continue their pursuits, expand their programs or launch new, innovative initiatives.

Endowed chairs provide partial support for research at the Stokes Institute, allowing skilled investigators and physician-scientists to pursue novel paths critical to understanding and treating pediatric diseases.

Last year, the endowed chair program represented more than $99 million of the Hospital’s total endowment, and provided nearly $5 million to support the work of the physicians and scientists holding the chairs.

The Hospital’s endowed chair program continued its unprecedented growth in fiscal year 2007 and today includes 65 chairs spanning all pediatric clinical specialties as well as specialized research programs and services.

The Hospital introduced two new endowed chairs in fiscal year 2007, supporting physicians in orthopaedics and radiology.
Dr. Bong S. Lee
Endowed Chair in
Pediatric Orthopaedics

Dr. Robert A. Zimmerman
Endowed Chair in
Pediatric Neuroradiology

support

v. {suh-"pohrt"}
1. to serve as a foundation for without giving way;
2. to sustain by supplying a foundation
The Dr. Bong S. Lee Endowed Chair in Pediatric Orthopaedics will provide funding for research and other initiatives for children with orthopaedic injuries or malformations.

The chair is named in honor of world-renowned hand surgeon Bong S. Lee, M.D. Dr. Lee is the director of Pediatric Hand Surgery at Children’s Hospital and has helped countless children since 1971. Dr. Lee has published extensively in medical journals and leading orthopaedic textbooks, and continues to serve as visiting professor at a number of institutions throughout the world.

His wife, Mi-Wha Lee, M.D., completed a pediatric residency at Children’s Hospital. She now serves as a school physician for the Philadelphia School District.

The Dr. Bong S. Lee Endowed Chair in Pediatric Orthopaedics is still pending appointment of a chairholder.

In addition, the Radiology Associates of Children’s Hospital, a physician practice plan representing the Department of Radiology, established an endowed fund to support a chair in neuroradiology.

Robert A. Zimmerman, M.D., chief of Neuroradiology/MRI, has been appointed to hold the endowed chair in pediatric neuroradiology. In addition to publishing and reviewing numerous scientific articles, Dr. Zimmerman was honored in 2002 with the American Society of Neuroradiology Special Achievement Award. The chair will support Dr. Zimmerman’s work to advance the research and academic mission of the Hospital’s programs in neuroradiology.
New Research Resources
<Unique Program Facilitates Discovery, Raises Hope for Cures>

Working closely with investigators and research staff, the Stokes Institute continuously anticipates emerging trends and technologies, considers all sources of potentially valuable research-related information, employs the unique skills and interests of investigators, and efficiently integrates the wealth of research data into potential clinical applications.

Supporting research to further scientific advancement may come in the form of equipment and services or, if warranted, specialized programs with widespread use throughout the Stokes Institute and Children's Hospital.

The Center for Biomedical Informatics (CBMi) is one of the ambitious new programs launched last year at the Stokes Institute to establish an information-based research program, as well as to support and facilitate research by the application of novel informatics solutions.

With hundreds of research studies and programs ongoing at the Stokes Institute and throughout the Hospital, harnessing all of the valuable information derived from research is essential to ultimately improving the health of children. The task, however, is complex given the multitude of sources for research-related information, the enormous and rapidly growing amount of biomedical data available, and the specialized skill sets, methods, and knowledge needed to derive value from research and clinical information.
CBMi meets those challenges by developing and applying ways to maximize the value of information relevant to all biomedical research, education and clinical activities at Children’s Hospital. The center’s focus on academic, educational, and service-based activities facilitates research and the development of innovative solutions that can quickly be distributed throughout the Hospital’s research and clinical communities.

This endeavor blends the emerging disciplines of bioinformatics and clinical informatics, which themselves require excellence in and integration of various knowledge domains, including biology, medicine, statistics, mathematics, linguistics and computer science. Nearly two dozen Stokes investigators bring their expertise to CBMi, and the center currently interacts with more than 80 research groups at Stokes.

CBMi provides comprehensive bench-to-bedside applications by developing and employing knowledge in such areas as electronic health record-driven clinical decision support, clinical data capture and storage, natural language processing, biomedical knowledge representation, and high-throughput genomic and functional genomic analysis for clinical application.

A major focus of the interdisciplinary center is on developing and providing educational initiatives and student sponsorship. Recognizing that biomedical research has recently transitioned into an information-based science, CBMi aims to raise the skill level of all Stokes investigators for informatics, which is crucial for attaining research excellence in today’s biomedical environment. Training opportunities for investigators and clinicians interested in developing skills in research informatics are available through CBMi’s education unit, which coordinates seminar series, workshops, common interest forums, and the development of formalized training programs around current topics in informatics and information technology.

CBMi collaborates closely with other Hospital centers and units such as the Center for Applied Genomics and the Institute to Transform Children’s Health, as well as a wide range of Stokes and Hospital personnel, to develop methodologies and practices to more fully use integrated knowledge as it applies to pediatric disease understanding, diagnosis, intervention and prevention.
hope

n. [hop]

1. expectation or belief in the possibility or prospect of obtaining;
2. the feeling that what is wanted can be
CBMi’s research arm promotes sponsored research in informatics applicable to diseases of interest to Children’s Hospital research and clinical groups. The center also provides a structure for synergizing existing Hospital-based informatics research and activities through a lab affiliation mechanism.

A service unit provides bioinformatics assistance to investigators to complement existing resources, support and training provided by Stokes. In addition, CBMi helps investigators optimize their use of methods and platforms developed internally for the discovery effort.

The Pediatric Research Consortium, which serves as the Hospital’s practice-based research network, provides assistance for any investigator seeking participation from primary care. CBMi’s Clinical Reporting Unit extracts and transforms data from the Hospital’s electronic data capture systems for both research and operational activities. Together, these groups currently support activities for more than 50 ongoing studies.
“The way in which cutting-edge research is performed has fundamentally changed in recent years,” says Peter White, Ph.D., the center’s director. “Biomedical research has traditionally focused upon how to generate data rather than how to analyze it, but recent advancements in technology have overwhelmed researchers with analytical challenges.

“As an encompassing strategy to meet these challenges, CBMi was created to represent a unification of diverse, but interrelated, informatics disciplines under a single organizational entity. We aim to empower researchers, clinical staff, patients and families to most effectively use the ever-expanding totality of pediatric health information. In turn, these processes are expected to result in more effective pediatric healthcare interventions.”
Innovation Fueling Progress
Innovative Technique Aims to Control Blood Loss

Severe blood loss can lead to death if not treated quickly and effectively. While severe blood loss is often associated with bleeding disorders such as hemophilia and von Willebrand disease, it also occurs in many common traumatic injuries, such as automobile accidents.

Understanding and identifying the complex molecular interactions associated with blood coagulation is the main research interest of Rodney M. Camire, Ph.D., Division of Hematology. Dr. Camire’s research is designed to serve as a key first step in the development of pharmacologic agents aimed at controlling bleeding.

Dr. Camire’s work over the past several years, in collaboration with Howard Hughes Medical Institute Investigator Katherine A. High, M.D., has contributed to two U.S. patent awards focused on methods to enhance clotting. More recently, his research, with the assistance of Valder Arruda, M.D., Ph.D., Division of Hematology, has led to a new finding that may provide a novel approach for halting severe blood loss. Children’s Hospital recently filed a patent application for this technology, and is negotiating with a global pharmaceutical company to license the technology.

The innovation pinpoints one interaction in a complex series of reactions that causes blood to clot. During this process, an activated enzyme called factor Xa in complex with factor Va rapidly activates thrombin — the protein ultimately responsible for the formation of a blood clot.
innovation

n. (in-nuh-vay-shuhn)
1. introduction of new things or methods for the first time;
2. the creation of a new device or process resulting from study and experimentation
Dr. Camire’s technology focuses on variant forms of factor Xa that circulate in a partially inactive state and are resistant to natural inhibitors. These variants, however, are fully able to cut prothrombin and activate thrombin when combined with factor Va. The advantages of these variant forms are that they can potentially stay in the circulation for a long period of time and only “turn on” or become active when a bleeding episode arises.

“This discovery has great potential for therapeutic application in treating a variety of bleeding disorders,” says Dr. Camire. “For example, factor Xa variants could be given to patients with hemophilia who have developed inhibitors against the standard replacement therapies or applied to patients who need enhanced clotting to control traumatic bleeding.”

Dr. Camire’s discovery stands to be developed into a direct competitor to a popular coagulation product on the market. Initial studies of the new discovery show great promise and the discovery could provide a significant advancement in the treatment of patients who have severe bleeding.

Future research, in partnership with industry, will examine how long factor Xa variants stay active in the blood in certain models with hemophilia A and B. After learning more about additional factor Xa variants that may have different benefits and developing a commercial production strategy, research will focus on preparation for and performance of preclinical studies of factor Xa variants.
<Mourning Their Loss, Celebrating Their Legacy>

The Children’s Hospital community mourned the passing of two of its innovators, whose pioneering research garnered national attention, contributed significantly to the understanding of pediatric disease and improved the lives of countless children throughout the world.

Gertrude Henle, M.D., collaborated with her husband, Werner Henle, M.D., for more than 45 years in virus research at Children’s Hospital. Their groundbreaking investigations prompted the National Library of Medicine to refer to the duo as “a prodigious force in virology, immunology and viral oncology during the second half of the twentieth century.”

The Henles demonstrated the effectiveness of an influenza vaccine, developed a diagnostic test for mumps, and collaborated on the use of gamma globulin to combat infectious hepatitis. Their work on viral infections laid the groundwork for scientists later to discover interferon.

The Henles were particularly notable for studying Epstein-Barr virus, however. They first showed that the virus was linked to mononucleosis, and later demonstrated that it contributed to two types of cancer.

Gertrude Henle was elected to the National Academy of Sciences in 1979, one of relatively few female members of that organization at the time. With her husband, she received numerous honors, including the Bristol-Myers Award for Distinguished Achievement in Cancer Research, the Robert Koch-Medaille (a German honor), the Mead Johnson Award for Research in Pediatrics, the Virus Cancer Program Award of the National Cancer Institute and The Gold Medal of The Children’s Hospital of Philadelphia, awarded in 1983.

Dr. Henle died in September 2006 at age 94.
For 41 years Stanton Segal, M.D., served as a distinguished member of the faculty of the Department of Pediatrics, helping to shape the research program at Children’s Hospital and introducing new technologies to advance pediatric metabolic research.

Dr. Segal established what is now the Division of Child Development, Rehabilitation and Metabolic Disease. He introduced mass spectrometry and nuclear magnetic resonance for metabolic research, and he began a metabolic diagnostic laboratory at Children’s Hospital that is now one of the premier laboratories in the country for the study of patients with inborn errors of metabolism.

Dr. Segal’s expansive research program focused on inherited disorders of membrane transport and disorders of carbohydrate metabolism, particularly galactosemia. His comprehensive knowledge of human biochemistry and its disorders led to numerous research grants to pursue his highly original and productive investigations in these areas. Several of his trainees have become world-renowned authorities in the field of metabolic diseases.

Dr. Segal’s contributions to the current understanding of the inborn errors of metabolism earned him international recognition, and his nearly 50 years of dedicated research have made a lasting impact in the field of metabolic diseases.

An indefatigable worker, Dr. Segal was actively involved in the operation of his research laboratory and the publication of research articles until the time of his death on April 16 at age 79.
Guiding the Evolution of Technology From Discovery to Marketplace

The Stokes Institute is widely known for its discoveries and innovations that advance the health of children. To further its mission to serve as the preeminent pediatric research institution in the world, the Institute provides investigators with valuable research facilities and has dedicated resources to protect the intellectual property that can develop from the Hospital's vibrant research programs.

By obtaining patents for intellectual property, Stokes safeguards innovations and ensures that the fully developed concepts and products can realize their full potential. The U.S. and Canada issued the following patents during fiscal year 2007 for technologies developed by Children's Hospital investigators.

Patent Awards:

- Active Licenses: 18
- Patents Issued: 5
- Patent Applications Filed: 48
- Invention Disclosures Received: 32
- FY 2007 License Revenues: $7,259,841
Beverly Emanuel, Ph.D., chief, Division of Human Genetics and Molecular Biology, and colleagues received a patent in April for methods for detecting genetic deletions and mutations associated with DiGeorge syndrome. The technology identifies whether there are less than two functional copies of the DiGeorge syndrome critical region loci that would increase the likelihood of the syndrome. The invention includes probes and primers as well as diagnostic kits. CA Patent 2,120,336

Former Children's Hospital investigator Thomas Genetta, Ph.D., Division of Neonatology, received a patent in July 2006 for a molecular marker for the diagnosis of late-stage tumor progression. The cellular localization of a protein called ZEB is a key indicator of the stage of tumor development. This localization can be detected with a variety of methods, including antibodies. An antibody or anti-sense reagent can be used to detect the expression levels and sub-cellular localization of the ZEB protein. Nuclear localization indicates a later stage of tumor development. US Patent 7,078,180

Calcification is a major factor that reduces the lifecycle of bioprosthetic implants. A patent awarded in January to Robert Levy, M.D., and Ivan Alferiev, Ph.D., Division of Cardiology, shows that a substance called mercapto-bisphosphonate can be used in combination with triglycidyl amine crosslinking to better protect a bioprosthetic implant from calcification. Such enhanced protection will extend the lifecycle of bioprosthetic implants like heart valves and artificial tendons and ligaments. US Patent 7,156,881

Rodney Camire, Ph.D., and Howard Hughes Medical Institute investigator Katherine High, M.D., Division of Hematology, received a patent in May for the use of a "Mini Factor VIII" gene for the treatment of hemophilia A. This truncated, active form of human factor VIII gene can be used in human gene therapy for the hemophilia condition. US Patent 7,211,558

Drs. High and Camire, along with two collaborators, also developed methods of modifying vitamin K-dependent proteins with maximal gamma carboxylation. Vitamin K-dependent proteins, like factor X, that are maximally carboxylated in this way can lead to a better understanding how these proteins work and how conditions like hemophilia may be treated. US Patent 7,220,849
The Stokes Institute is determined to maintain and surpass the level of success in fiscal year 2007. To achieve this goal, the Institute provides access to the most valuable and effective resources, research facilities and intellectual property resources. Last year the Stokes Institute established two unique faculty committees to advance science through shared core facilities and to protect the intellectual property arising from research.

The Institutional Core Advisory Committee at Stokes oversees and guides the Institute’s shared core facilities, designed to facilitate discovery. The committee reviews existing policies and procedures, examines core organizational structures and utilization, ensures the facilities meet the evolving needs of investigators, and advises the Institute about the establishment of new cores.
At the intersection of scientific research and the biomedical marketplace is the Office of Technology Transfer, which works to protect the Hospital’s interest, its faculty, and its intellectual property — and generate revenue in the process.

The second faculty committee established by Stokes, the Institutional Intellectual Property Advisory Committee, assists Technology Transfer in assessing the invention disclosures received by the Hospital and providing guidance on patent prosecution as well as other intellectual property-related decisions.

With members possessing a broad representation of scientific strengths, the committee also participates in strategic planning and works with faculty to take advantage of Technology Transfer’s expertise in order to protect inventions and discoveries stemming from research at the Stokes Institute.
The War For Talent
Whether in the laboratory, the clinic or at a computer, Stokes investigators are engaging in innovative, state-of-the-art research with a common goal – improving the health of children throughout the world.

Numerous investigators joined the Stokes Institute last year, adding to its growing and diverse talent pool. The research interests of these investigators include all of the pediatric subspecialties like oncology and cardiology, and extend to other critical research areas as well, including radiology, pathology and psychology.

The future of research at Children’s Hospital – and the improvement of healthcare for children – rests with these talented individuals, some of whom are featured here.
Sriram Balasubramanian, Ph.D., Center for Injury Research and Prevention, focuses on biomechanics and orthopedic research. He specifically investigates the response of the cervical and thoracic spine, the spine in the areas of the neck and upper back, during automotive accidents. He is looking at how these areas of the spine in children and adults respond to conditions that mimic a low-speed frontal impact, and studies the motion of the neck during such an event. Dr. Balasubramanian will apply these data to guide the development of an accurate model of a pediatric cervical spine for a child crash test dummy.

Bone marrow transplantation is generally used to treat disorders of the blood, but it has the potential to contribute to a number of other therapeutic applications. Edwin Horwitz, M.D., Ph.D., Division of Oncology, is studying the potential of using bone marrow cells to treat osteogenesis imperfecta (OI), a genetic bone disorder. He found that bone marrow transplantation and additional marrow cells can engraft in bone and generate clinical benefits in children with OI. Dr. Horwitz is now focusing on increasing the clinical improvements in these patients and plans to open two clinical studies to examine the therapeutic benefits and safety of bone marrow cells for OI. He ultimately wants to enhance the therapeutic potential of bone marrow cell transplantation for children with other catastrophic illnesses.
Clinical pharmacologist John Mondick, Ph.D., Division of Clinical Pharmacology and Therapeutics, has a solid research background in clinical drug development in the pharmaceutical industry. His current research focuses on the application of mathematical modeling and simulation techniques to problems in pediatric clinical pharmacology. Dr. Mondick’s research interests include investigating sources of pharmacokinetic and pharmacodynamic variation, the application of novel modeling and simulation approaches to pediatric pharmacology, simulation and design of clinical trials, and developing rational dosing guidance in pediatric populations.

Struan Grant, Ph.D., Division of Human Genetics and Molecular Biology, conducts research on the genetics of pediatric metabolic disease. During more than 10 years of research, he has made several significant findings by working with key populations around the world that provide a unique insight into how to isolate human disease genes. He continues this approach by using the high-throughput genotyping technology available in the Center for Applied Genomics. He works toward the isolation of genes involved in childhood obesity and pediatric bone strength, two traits that are strongly determined by genetic factors, with the hope of reducing the global prevalence of obesity and osteoporosis.
Hospital Recognizes Vaccine Inventors With Prestigious ‘Gold Medal’ Award

H Fred Clark, D.V.M., Ph.D.; Stanley Plotkin, M.D.; and Paul Offit M.D., chief of Infectious Diseases, Maurice R. Hilleman Endowed Chair in Vaccinology, and director of the Hospital’s Vaccine Education Center
RotaTeq®, the rotavirus vaccine developed by investigators at Children’s Hospital and The Wistar Institute, continues to save the lives of children throughout the world after receiving approval by the Food and Drug Administration less than two years ago.

Today, the vaccine has been approved for use in 61 countries and launched in 22 of those countries, including Canada, Mexico, Japan and many parts of Europe. More than two million courses of the three-dose regimen have been administered to combat the single largest infectious disease killer of infants and young children worldwide.

Children’s Hospital recognized the achievements of three scientists for their discovery of the rotavirus vaccine by awarding each of them The Gold Medal of The Children’s Hospital of Philadelphia, an honor last awarded in 1983.

H Fred Clark, D.V.M., Ph.D.; Stanley Plotkin, M.D.; and Paul Offit M.D., chief of Infectious Diseases, Maurice R. Hilleman Endowed Chair in Vaccinology, and director of the Hospital’s Vaccine Education Center, invented RotaTeq®, which is the only vaccine available in the U.S. for use against rotavirus gastroenteritis.

Rotavirus affects nearly all children at some point, often with mild symptoms, but in other cases with severe and potentially life-threatening diarrhea and dehydration. Among children under the age of 5 in the United States, it is estimated that 2.7 million episodes of rotavirus occur each year, leading to approximately 250,000 emergency room visits and up to 70,000 hospitalizations. Worldwide, approximately 600,000 children die each year from rotavirus.
Drs. Clark, Offit and Plotkin led laboratory studies of the rotavirus vaccine at Children’s Hospital and Wistar between 1980 and 1991. Since 1991, the vaccine has been developed for commercial use by Merck & Co. Inc., which conducted extensive clinical trials.
Created in 1963, The Gold Medal of The Children’s Hospital of Philadelphia is awarded to individuals or institutions that have enhanced the welfare of children through major contributions in medicine, surgery and other specialties; psychiatry and social sciences; education and research.

The Gold Medal was last awarded in 1983 to Gertrude Henle, M.D., and Werner Henle, M.D., for major contributions in diagnosis and disease prevention with the creation of the mumps and influenza vaccines. In 1981, C. Everett Koop, M.D., Sc.D., was awarded The Gold Medal for advancing the health of children through the development of pediatric surgery.
Providing additional guidance to the growing Stokes Institute is a new deputy scientific director, who joined the Hospital in July.

Tom Curran, Ph.D., FRS, oversees certain critical administrative aspects of research operations for the Stokes Institute, including the core facilities that support both laboratory and clinical research programs.

A world-renowned scientist, Dr. Curran has made numerous fundamental scientific contributions in the fields of neurobiology, signal transduction and cancer biology. He has authored more than 240 publications and holds the rare distinction of being listed as a high-impact scientist in three fields (neuroscience, molecular biology, and genetics and microbiology) by ISI HighlyCited.com, and was ranked fourth in the world in molecular biology and genetics from 1998 to 1992.

In addition to these outstanding academic credentials, Dr. Curran is also known as an outstanding teacher, mentor and administrator. He served as president of the American Association for Cancer Research in 2001 and on the board of advisors of the National Cancer Institute from 2000 to 2005. In 2005 he was elected to the Royal Society of London, U.K.

Dr. Curran continues his academic pursuits at the Stokes Institute by leading an interdisciplinary translational research center devoted to pediatric brain tumors. The center unites investigators from across the academic campus to focus on this important scientific and clinical problem.
leader

n. [lee-der]
1. a person who guides or inspires others;
2. a directing head or conductor
**protect**

v. /prəkt/  
1. to shield from injury or harm;  
2. to guard or defend from danger; to keep safe
The Food and Drug Administration has a longstanding commitment to protecting children enrolled in clinical trials by ensuring that research involving children embodies the best ethical and medical principles.

To further this goal, the FDA sought the insight and knowledge of Robert M. Nelson, M.D., M.Div., Ph.D., Department of Anesthesiology and Critical Care Medicine, and in October 2006 appointed him as a pediatric ethicist with the Office of Pediatric Therapeutics. The position is mandated by the Best Pharmaceuticals for Children Act.

Dr. Nelson’s ability to address the ethical issues surrounding pediatric clinical research is unparalleled. In addition to caring for critically ill children for the past 20 years, he has worked with parents and families and published widely on the ethical and regulatory issues in pediatric research and clinical care.

Dr. Nelson has also served as a consultant on ethical issues in research to the NIH, the Environmental Protection Agency, the FDA, the U.S. Department of Health and Human Services, and the Institute of Medicine.

While serving as the FDA’s pediatric ethicist, Dr. Nelson maintains his faculty appointments at the University of Pennsylvania and as director of the Children’s Hospital Center for Research Integrity, which advances the responsible conduct of pediatric research.
Avital Cnaan, Ph.D., chief, Division of Biostatistics and Epidemiology, was appointed to the FDA’s Pediatric Advisory Committee. The committee makes recommendations to the commissioner of the FDA regarding identification of research priorities related to pediatric therapeutics; the ethics, design and analysis of clinical trials related to pediatric therapeutics; pediatric labeling changes as well as adverse event reports for drugs granted pediatric exclusivity based on the Best Pharmaceuticals for Children Act; and any other matter involving pediatrics for which FDA has regulatory responsibility. Dr. Cnaan’s term is through June 30, 2010.

Terri Finkel, M.D., Ph.D., chief, Division of Rheumatology, was honored with election to the prestigious Henry Kunkel Society. The Kunkel Society was established in memory of Henry George Kunkel, a professor at Rockefeller University whose contributions to the field of basic and clinical immunology are legendary. He was perhaps best known for his pioneering and extensive studies on immunoglobulins. Dr. Finkel’s nomination honored her “seminal contributions to the fields of immunology and rheumatology,” in particular, in the areas of cell signaling in T-cell development and cell death in AIDS.

Stephan Grupp, M.D., Ph.D., Division of Oncology, received the Eagles Fly for Leukemia Lifetime Achievement Award, which recognizes medical, business and community leaders.

Flaura Winston, M.D., Ph.D., has been named a recipient of an AcademyHealth Health Services Research Impact Award for her efforts to protect children from injury and death in vehicle accidents.
Jordan Orange, M.D., Ph.D., Division of Allergy and Immunology, was elected secretary of the Basic and Clinical Immunology section of the American Academy of Allergy, Asthma & Immunology, the largest society in the U.S. for allergists and immunologists. Dr. Orange’s election will lead to the chair position from 2011 to 2013.

Beverly Emanuel, Ph.D., chief, Division of Human Genetics and Molecular Biology, received the Herbert and Esther Bennett Brandwein Award in Genetic Research from the Department of Genetics & Developmental Biology at the University of Connecticut.

Michael Bennett, Ph.D., director, Michael J. Palmer Metabolic Laboratory, received the “Outstanding Contributions in a Selected Area of Research” award from the American Association for Clinical Chemistry.

Elizabeth Alpern, M.D., M.S.C.E., Division of Emergency Medicine, and Theoklis Zaoutis, M.D., Division of Infectious Diseases, were elected to the Society for Pediatric Research.

Melissa Alderfer, Ph.D., Division of Oncology, received the Routh Early Career Award in Pediatric Psychology from the Society of Pediatric Psychology. The award recognizes significant contributions, accomplishments and evidence of leadership of an early career psychologist in the field of pediatric psychology.
Phyllis Dennery, M.D., chief, Division of Neonatology, received the Alfred Stengel Health System Champion Award. The award recognizes a Penn Medicine physician who has made significant contributions toward the clinical integration of the University of Pennsylvania Health System, along with a demonstrated commitment to the improvement of quality care.

Bret Rudy, M.D., Division of Adolescent Medicine, received the Red Ribbon Award for Research by the Center for AIDS Research in recognition of his continuing contribution in the area of HIV/AIDS research.

Fred Henretig, M.D., Division of Emergency Medicine, received the university’s Scott Mackler Award for Excellence in Substance Abuse Teaching.

Jane Lavelle, M.D., Division of Emergency Medicine, received Penn’s Blockley-Osler Award, which recognizes a member of the faculty at an affiliated hospital for excellence in teaching modern clinical medicine at the bedside.
Jordan Orange, M.D., Ph.D., Division of Allergy and Immunology, received the university’s Leonard Berwick Memorial Teaching Award, which recognizes a member of the medical faculty who in his or her teaching effectively fuses basic science and clinical medicine.

Lisa Zaoutis, M.D., Division of General Pediatrics, received the Dean’s Award for Excellence in Clinical Teaching at an Affiliated Hospital. The award recognizes clinical teaching excellence and commitment to medical education by outstanding faculty members from affiliated hospitals.

Donna McDonald-McGinn, M.S., C.G.C., Division of Human Genetics and Molecular Biology, received the Dean’s Award for Excellence in Medical Student Teaching by an Allied Health Professional.
Reengineering Stokes
<Meeting the Service Mission for the Research Community>

Maintaining pediatric research preeminence requires continuous evaluation and detailed plans for further growth and enhanced services to support discovery. Part of this evaluation includes assessing whether the Institute is structured to optimize the support of its mission and research community.

The Stokes Institute introduced a new organizational framework in 2007 aimed at fine-tuning and streamlining the services provided to investigators. Staying ahead of the curve, anticipating the needs of investigators and research staff, and having the vision and resources to implement changes and improvements ensure that investigators can in turn serve the Hospital’s most valuable resource — its patients and their families.

Under the direction of Philip Johnson Jr., M.D., chief scientific officer and senior vice president of the Stokes Institute, these administrative and scientific directors and managers provide the services needed to best support the research community at Children’s Hospital.
Guiding the Stokes Institute’s mission to be the preeminent pediatric institution in the world dedicated to translational research is Peter Adamson, M.D., director of the Office of Clinical and Translational Research. Peter oversees the transition of biomedical sciences into patient-oriented research with a pediatric focus, working with investigators to identify scientific opportunities and forge productive collaborations. Dr. Adamson, who also serves as the Hospital’s principal investigator for the Clinical Translational Science Award, strives to improve the clinical and administrative research infrastructure that supports investigators as they translate laboratory advances from bench to bedside.

As program director for Research Planning, Lynn Bevan-Watson coordinates the business process assessment and reengineering for those Stokes departments charged with implementing a centralized, Web-based system for research administration and research compliance needs. She also coordinates the Hospital’s initiative aimed at accreditation of its human subject protections program.

Integrating the research institute’s priorities into the Hospital strategic planning process is the primarily responsibility of Jeanne Buckley, Ed.D., who directs the Office of Research Planning. Jeanne develops, monitors, assesses and provides benchmark data on the Institute’s operating plan. She serves as project manager for the centralized, Web-based research administration compliance system, which will provide reliable data for assessment and reporting purposes. Jeanne also takes a lead role in evaluating Stokes’ programs and services, coordinating with various departments to prepare business plans for large institutional initiatives.
In addition to his thriving and world-renowned research, Tom Curran, Ph.D., serves as the deputy scientific director for Stokes, overseeing critical functions related to the Institute’s core facilities, intellectual property and research safety. He also takes a role in space planning for investigators and research staff, works with various departments to enhance faculty and academic activities, and facilitates interactions with the University of Pennsylvania through his role as an associate director of Translational Genomics at the university.

A specialized team within the Stokes Institute helps the research community with applying for, negotiating and managing funding to investigators. Sara Dubberly oversees these efforts in her role as director of Sponsored Projects and Research Business Management. Sara serves as the primary liaison with funders and peer institutions collaborating with Stokes investigators, and ensures the research community receives appropriate stewardship of externally provided resources, complies with all sponsor regulations and Hospital policies, and benefits from administrative practices that support and strengthen the scientific program.

Vision and oversight of the development and administration of biological, laboratory and chemical safety programs is provided by Ray Colliton, the Institute’s research safety program officer. Working closely with the Hospital’s Environmental Health and Safety department, Ray and his team partner with investigators and staff to develop policies and procedures that are relevant, practical and comply with government regulations. He also coordinates the Institutional Biological Safety Committee in collaboration with the Office of Research Compliance and Regulatory Affairs.
Managing the space and resources needed to support the Hospital’s growing research program is a task overseen by Howard Eck, Research Resources director. Howard heads a team that partners with faculty and staff to establish the physical infrastructure required to support the research enterprise. He manages minor renovation projects, relocation of research programs, and faculty and staff work requests. In addition, Howard leads his department’s efforts in strategic and long-range planning, research space construction and assessment, and inventory development.

The integrity of the research institute’s compliance program is promoted through the department led by Carrie Fisher, Ph.D., who serves as director of the Office of Research Compliance and Regulatory Affairs. Carrie supervises all administrative and reporting aspects of the Hospital’s Institutional Review Board, Institutional Animal Care and Use Committee and Conflict of Interest Committee. She focuses her efforts on identifying and developing compliance policies for new areas of research risk; serving as the Stokes expert on compliance matters; and developing a comprehensive compliance training program.

Investigators and their support staff need the highest quality goods at the best overall price to conduct their research efficiently. Kim Gossin, Research Acquisitions and Contracting manager, and her team assist divisions with expediting orders, processing returns/repairs and providing requested reports. She also administers price protection agreements for services and supplies by managing the bidding process, identifying bid opportunities, and maintaining a bid cycle for routinely purchased items and services.
Protecting the rights of patients participating in research studies has long been at the center of clinical trials at Children’s Hospital. Barbara LoDico, director of Human Subjects Research, administers the Hospital’s IRBs and manages the IRB staff. She also collaborates with various Stokes Institute directors to ensure that IRB policies and procedures, educational activities and operational systems enable the IRBs and the Hospital’s human subjects protection program to function effectively within all of the required regulatory requirements.

Communicating the many discoveries and accomplishments of the Institute’s investigators is managed by Jennifer Long, who leads the Research Communications department. Jennifer directs internal and external communications aimed at describing and promoting Stokes research, and oversees a team of writers and designers who provide communication services for administration, investigators and research staff. She also works closely with various Stokes and Hospital departments as well as investigators to enhance media exposure of Stokes, produce research publications and Web content, and enhance internal communications.

Administrative and financial oversight of the Stokes Institute’s numerous scientific core facilities is provided by Lisa MacDowell, administrative director of Core Services. Lisa helps set the cores’ strategic directions and priorities and oversees all administrative functions for the cores and recharge centers. She also coordinates the cores’ planning, budgeting and marketing efforts; Web site development and maintenance; and metric and benchmark reporting.
The Institute’s strategic and operational business plans and goals are aligned with the goals of the Hospital’s Human Resources Research Service team through the services provided by Denise Outlaw, Research Human Resources manager. Denise investigates and resolves discrimination and harassment charges, and manages the recruitment and development of staff. In addition, Denise provides advice on staff retention, employee and labor relations, and performance management.

Leading the Hospital’s intellectual property management and commercialization efforts is Ellen Purpus, Ph.D., who serves as director of the Office of Technology Transfer. Ellen oversees a team that aims to effectively manage the Institute’s growing technology portfolio from early-stage disclosures to late-stage licensure and commercialization.

More than half of the research at Children’s Hospital involves complex clinical trials. Supporting these studies is the Clinical Trials Office, directed by Lisa Speicher, Ph.D. Lisa supports clinical investigators by assisting with submissions to the Hospital’s Institutional Review Board, developing budgets for clinical research and preparing applications to the FDA. Lisa also serves as associate director for the Office of Clinical and Translational Research. In this role she facilitates research collaborations, matches investigators to funding opportunities, and develops procedures to enhance clinical and translational research.
Creating an environment that promotes the success of all faculty members is the primary aim of the Office of Faculty Development, led by Virginia Stallings, M.D. Virginia facilitates the investigators’ successful transition from fellow to faculty, encourages and supports activities that lead to promotion, engenders the spirit of mentorship for the future and provides tools for achieving work-life balance for faculty.

Mary Tomlinson, vice president of Research Administration, helps ensure the many complex facets of administration at the Stokes Institute run efficiently and collaboratively while meeting the evolving needs of investigators and research staff. Mary specifically oversees grants management, comprehensive business functions, financial planning and reporting, communications, laboratory animal services, facilities and information systems at the Stokes Institute, and plays a key role in guiding organizational changes.

Coordinating the research projects and budget accounting system for the Stokes Institute is a responsibility of Research Finance Director Steve Wiley, who also reviews the compliance of expenditures, and prepares financial reports for external sponsors and administration. Steve and his team coordinate audits, ensure compliance with federal cost principles, assist investigators with closing out sponsored projects, and maintain responsibility for a variety of tasks for budgeting, financial planning and monitoring Stokes’ financial position.
Under the direction of Wendy Williams, Ph.D., the Research Education department assesses and facilitates the design, delivery and evaluation of Hospital-wide research education and training programs. Wendy delivers training or guides staff to train others using instructional methods and delivery, and works on the development of training materials, curriculum and evaluation methods. She also consults Stokes leadership to meet the strategic learning and effectiveness needs of the research enterprise, and chairs the Committee on Postdoc Affairs.

The information technology needs of the research community are met by Research Information Systems, directed by Pete Witzleb. Pete plans, coordinates and implements the IT and support needs for the research community, manages a unit that provides specialized IT support and serves in an advocacy role with senior leadership for research IT issues. He also engages in active brokering and coordination across providers of research IT at the Hospital, and provides capabilities and expertise for advanced scientific computing for research.
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<Financial/Award Information>

Over the past several years, federal funding supporting research has been static or decreased, and state budgets, which provide additional support for research, have been operating with large deficits.

Despite these statistics, annual funding to the Stokes Institute continues to increase, a testament to the Institute's commitment to pursuing new avenues for growth, partnerships and collaborations that allow for Stokes to continue its unprecedented growth in a time of fiscal reserve. The Stokes Institute's growth in total grant revenue continues to greatly outpace the NIH's budget growth.

The 2007 budget for research neared $200 million and the Stokes Institute had more than 325 principal investigators with more than 600 awards, 60 percent of which came from the NIH. There were approximately 1,200 research employees at the Hospital, not counting principal investigators and faculty.

Provided here are details on the Stokes Institute's financial performance during fiscal year 2007.
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