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PEDIATRIC CLINICAL RESEARCH CENTER
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Prepared for:

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Executive Summary

The goal of the PCRC demonstration project was to establish an organized administrative infrastructure and state-of-the-art information systems to support pediatric clinical and translational research in the All Children's Hospital research community in furtherance of the Maternal and Child Health Bureau's mission to improve health outcomes and service access for children and mothers. The collaborating entities included three of the major health related entities in the Greater Tampa Bay area: All Children's Hospital, the University of South Florida Health Sciences Center and H. Lee Moffitt Cancer Center and Research Institute.

The aims of the demonstration grant project were as follows:

- To create an administrative infrastructure that will support the testing of the efficacy of treatment, and the implementation of the processes involved in transferring research results to treatment settings.
- To establish a service center for pediatric investigators that will facilitate the day-to-day research process and assist the research patients in a supportive and efficient environment
- To provide a vehicle for interdisciplinary basic and clinical pediatric research for principal investigators from All Children's Hospital, the University of South Florida Health Sciences, and the Moffitt Comprehensive Cancer Center.
- Significantly contribute to the University of South Florida's and All Children's Hospital teaching and research mission by providing resources and support to the growth of programs in Developmental Hematopoiesis, Immunology/HIV, Pulmonology Disease, Hematology/Oncology, Cytogenetics, Clinical Genetics, and Health Policy
- Develop a dedicated informatics network for pediatric research data management, and create a Genetics Informatics Network, expanding the All Children's genetics research program

All of the aims for this grant project were accomplished. ACH/USF research investigators have established access to administrative, fiscal, clinical, informatics, and laboratory services dedicated to supporting cutting edge pediatric research activities. An aggressive strategy of research program development has increased the quantity and quality of research activities in the research community, provided support for new investigators to launch their pilot projects, and contributed to the growth of All Children's core clinical programs. Dedicated genetics research resources were acquired which provide real-time access to a variety of Web-based genetics research tools and data sources.

I. Introduction

Improvements in the prevention, diagnosis, treatment and care for children affected with congenital and acquired acute and chronic illnesses can only be accomplished through the investment in infrastructures targeted to support pediatric research. However, there are less than fifteen pediatric general clinical research centers within children's hospitals and academic medical centers in the United States dedicated to pediatric research, and none of these centers are located in the Southeastern United States.

In collaboration with the University of South Florida's Department of Pediatrics, All Children's Hospital embarked on a comprehensive program to improve the overall clinical, translational and basic sciences research infrastructure for pediatric research in the Saint Petersburg/Tampa area. An increasing number of extramurally funded research investigators and physician/scientists recruited by the University of South Florida, All Children's Hospital and the Moffitt Cancer Center and Research Institute had increased the quantity and quality of clinical and translational research projects occurring within the All Children's research community. However, the lack of an administrative infrastructure with clinical, laboratory and informatics resources dedicated to supporting pediatric research within the Hospital's biomedical community was inhibiting the growth and development of these translational, clinical and outcomes research activities.

The most successful infrastructure model for supporting translational and clinical research on-site at a medical institution has been the "General Clinical Research Center (GCRC)" program supported by the National Center for Research Resources (NCRR)/National Institutes of Health. NCRR-funded GCRCs are designed to support investigator-initiated clinical research projects within the respective outpatient or inpatient clinical environment. The GCRC Program provides financial support for the components essential to clinical research: operating expenditures; salaries of key personnel including nurses, biostatisticians, administrators, core laboratory staff, and computer personnel.

It was determined that a Center with an organized administrative infrastructure and state-of-the-art information systems had to be established if the scientific biomedical community at All Children's was to become a nationally recognized center for pediatric medicine and research, and, before an application could be submitted to the NCRR that had a reasonable expectation of competitive funding. The MCHB demonstration grant funding enabled the development of a specific infrastructure reflecting the GCRC model at All Children's Hospital.

Purpose, scope, and methods of the investigation

The purpose of this demonstration grant project was to establish an organized administrative infrastructure and state-of-the-art information systems to support pediatric clinical and translational research in the All Children's Hospital research community. The intent of the project was to support and pursue research compliant with the Maternal and Child Health Bureau's mission to improve health outcomes and service access for children and mothers. The

collaborating entities included three of the major health related entities in the Greater Tampa Bay area: All Children's Hospital, the University of South Florida Health Sciences Center and Moffitt Cancer Center and Research Institute.

The aims of the demonstration grant project were as follows:

- To create an administrative infrastructure that will support the testing of the efficacy of treatment, and the implementation of the processes involved in transferring research results to treatment settings
- To establish a service center for pediatric investigators that will facilitate the day-to-day research process and assist research patients in a supportive and efficient environment
- To provide a vehicle for interdisciplinary basic and clinical pediatric research for principal investigators from All Children's Hospital, the University of South Florida Health Sciences, and the Moffitt Comprehensive Cancer Center.
- Significantly contribute to the University of South Florida's and All Children's Hospital teaching and research mission by providing resources and support to the growth of programs in Developmental Hematopoiesis, Immunology/HIV, Pulmonology Disease, Hematology/Oncology, Cytogenetics, Clinical Genetics, and Health Policy
- Develop a dedicated informatics network for pediatric research data management, and create a Genetics Informatics Network, expanding the All Children's genetics research program

We are pleased to report the successful completion of all of the aims for this grant project. Prior to the initiation of the Pediatric Clinical Research Center (PCRC) demonstration grant project in 2003, there was no formal research infrastructure in the ACH research community which could adequately support translational and clinical research. Now, ACH/USF research investigators have easy access to administrative, fiscal, clinical, informatics, and laboratory services dedicated to supporting their pediatric research activities. Our aggressive strategy of research program development has increased the quantity and quality of research activities in the research community, provided support for new investigators to launch their pilot projects, and contributed to the growth of All Children's core clinical programs. Lastly, we expanded our dedicated genetics research resources by acquiring high throughput sequencing technology and portal software which provides real-time access to a variety of Web-based genetics research tools and data sources.

II. PCRC Infrastructure

The following sections provide a more detailed description of the Pediatric Clinical Research Center resource infrastructure created under this demonstration grant.

Using the GCRC model, we created the Pediatric Clinical Research Center (PCRC), a point of service for investigator-initiated pediatric clinical and health outcomes research. The PCRC provides research investigators with assistance in study design and implementation including nursing, regulatory, biostatistics consultation, database design and storage, and sample processing. The components of the PCRC include: (1) a Clinical Core which includes nursing services and investigational pharmacy; (2) a Laboratory Core for laboratory specimen processing

and storage repository and a Biological Safety Containment Level 3 (BSL-3) laboratory; (3) a Genetic Sequencing Core with high throughput genetic sequencing technology for mutational analysis of human genetic disease; (3) an Informatics Core; (4) a Health Policy and Outcomes Core. These cores are co-located on the All Children's Hospital Campus in geographic proximity of a combined inpatient and outpatient health care setting.

Administrative Core

The Administrative Office is located in the first floor of the ACH Business and Technology Center, adjacent to the hospital and clinical areas, and provides offices and a conference room for the PCRC administrative staff. Additionally, computer workstations are available for students, residents, fellows and investigators who are conducting research with PCRC support. The management staff includes the Administrative Manager, Grants Coordinator, Nurse Manager, Research Nurse, Outcomes Researcher, and Informatics Manager, and Systems Analyst. In addition to facilitating the day-to-day operations of the PCRC, the staff is a resource to investigators in protocol design, implementation, and assistance in the management of grants and finances Biostatistics services are also provided on a consultative basis.

Clinical Core

The Clinical Core service consists of two components: research nursing and investigational pharmacy.

Nursing

The PCRC research nursing staff is comprised of skilled pediatric and neonatal registered nurses to assist principal investigators in the coordination and performance of scatterbed and outpatient studies. Services include: development of a protocol implementation plan; coordination of protocol implementation; screening and identification of eligible subjects; administration of research interventions; assistance with procedures and specimen collection; data collection; and research record management

Investigational Pharmacy

The Investigational Pharmacy was established to provide support for clinical drug research at All Children's Hospital, and is located within the Inpatient Pharmacy. Services include the receiving, storing, dispensing and monitoring of investigational drugs to insure that all drug studies are conducted safely and in compliance with federal, state, JCAHO and IRB regulations. The PCRC acquired a 50% FTE pharmacist to supervise the sterile mixing and storage of infusion products and biological agents of investigation drugs. The Investigational Pharmacist works directly with investigators to facilitate accurate accountability of investigational drug products.

Laboratory Core

The components of the Laboratory Core include the Bio-Safety Level 3 Laboratory and the Specimen Processing and Repository Laboratories, which are located on the fourth floor of the ACH/USF Children's Research Institute.

Biological Safety Level 3 Laboratory

The Biological Safety Level 3 Laboratory (BSL-3) meets current Centers for Disease Control guidelines. This space consists of approximately 400 square feet with an adjacent preparation

room. It is equipped with air-flow systems for biological containment, and a biological safety seal entrance way, a dual access Autoclave/Sterilizer designed specifically for a BSL-3 laboratory, a bench top refrigerated centrifuge, two biological safety cabinets, a -85°C upright freezer with CO_2 backup, a liquid nitrogen storage system, a double-bank incubator, an inverted microscope with digital camera, a microfuge, and PC computer system.

Sample Processing and Specimen Repository

The Sample Processing Laboratory and Specimen Repository Core Laboratories are located in approximately 1000 square feet of space on the fourth floor of the USF/ACH Children's Research Institute (CRI), in close proximity to the outpatient and inpatient services of the hospital. The necessary equipment for rapid specimen processing and storage, including centrifuges and biological safety cabinets are available. The Laboratory houses two biological safety cabinets, a floor model swinging bucket centrifuge, a cell analyzer, inverted microscope, standard microscope, refrigerator and freezer for storage of media and reagents, and a SANYO Model MCO-36AIC upright dual incubator for cell culture. An adjacent room houses four –85° Upright Freezers with CO backup, alarm, and long term cryopreservation system containing a -190° C liquid Nitrogen Storage tank capable of storing up to 36,000 individual samples. A third component of the laboratory, designed for the separation of the cellular components of human blood and assessments of cellular function, contains an Milyenyl Biotech Automax cell separator and ELISA plate reader and washer.

Genetics Core

As we progressed in the development of the PCRC, we identified a significant need for more sophisticated laboratory resources to enhance our existing laboratory core and expand our capabilities for mutational analysis of human genetic disease. In the last 18 months of the grant period, we enhanced our cellular and genetic laboratory resources with the addition of a Leica CM30505 Cryostat and a Bio-Rad CHEF Mapper XA, which is a pulsed field gel electrophoresis unit that allows the resolution of extremely large DNA strands. These systems complement the other PCRC high throughput genetic sequencing technology, which was purchased through another funding source. In addition, the PCRC partnered with the University of South Florida to purchase a FACSAria 3 Laser (13 color) Cytometry system to provide crucial flow cytometry analysis for cellular and genetic studies in all biomedical areas of interest. All of this technology is installed in the ACH/USF Children's Research Institute, and has been utilized by ACH/USF pediatric researchers conducting research in molecular genetics, allergy and immunology, cardiac development and congenital heart disease, immunologic tolerance in organ transplantation.

Informatics Core

The Informatics Core provides access to hardware, software and data management services for investigators who are conducting research under approved PCRC protocols. Software for statistical analysis, web portal access, and the HCUP databases have also been installed and are available for use.

In the past two years, a significant investment in financial and personnel resources has been directed to the purchase and installation of **iRIS** (Integrated Research Information System), a research information software solution to support the Pediatric Clinical Research Center, as well

as the larger research enterprise of All Children's Health System, including the Institutional Review Board and Research and Grants Administration. The purpose of this robust web-based solution is to facilitate a seamless transition from the initiation of a study application by a principal investigator, to an electronic and automated review by the Institutional Review Board, and the subsequent efficient management of multi-site studies. The **iRIS** system is accessible through the Research section of the All Children's web site. The IRB module has been implemented and principal investigators are submitting protocols through the system.

The information technology resources were expanded this past summer with the installation of the Websphere Bioinformatics Portal software, which is being used by ACH/USF molecular genetics researchers. This portal software provides a standard means of access to a variety of Web-based tools and data sources, including Pub Med, GenBank, BLASTn, GeneID and BLASTp, in an optimized and performant way via a portal window, providing an integrated, web-based workspace to screen novel genes. The Websphere infrastructure also provides the platform for a designated Research Portal, which allows each investigator to create an individualized "on-ramp".

In addition to the technological infrastructure, the Informatics personnel provide direct service to investigators by assisting with database design and implementation and data translation services. Several computers and peripherals located in the PCRC Administrative Office are available to investigators including workstations, laptops, and printers.

Outcomes Core

The research emphasis of the Outcomes and Health Policy Core is on the quality, safety and outcomes of hospital care for children and adolescents. The primary research aims include exploring the relationship between the volume and outcomes of identified diseases or procedures; examining the relationship between policy and organizational characteristics and child health outcomes; and investigating the quality and outcome of care in children with chronic conditions and special health care needs. The majority of research is conducted using secondary analysis of large state level and national level administrative databases, primarily the National and State pediatric inpatient and ambulatory care databases from the Healthcare Costs and Utilization Project (HCUP).

Dr. Lisa Simpson, All Children's Guild Endowed Chair in Child Health Policy and Chair of the USF Department of Pediatrics, Division of Child Health Outcomes, led the team of research professionals to pursue PCRC-funded and PCRC-supported quality and outcomes of care studies. These studies resulted in numerous posters and platform presentations at national, regional and state conferences including: 2006 Pediatric Academic Society Meeting (PAS), Academy of Health, National Initiative for Children's Healthcare, and the 5th Annual Florida Medicaid Research Conference.

III. Organization/Leadership

The management structure of the PCRC was modeled after the GCRC management model. The leadership team included the Program Director and two Associate Program Directors who together provided administrative oversight for the PCRC, and individually supervised a specific

PCRC core area. Dr. John Sleasman (Program Director), Dr. Lisa Simpson (Associate Program Director) and Dr. Gary Litman (Associate Program Director) are full-time members of the University of South Florida Health Sciences Center, Department of Pediatrics, and are all productive investigators with independent peer-reviewed research support.
In November 2006, Dr. Lisa Simpson, who had directed the Outcomes Core since its inception, announced her resignation from the University of South Florida, effective January 2007. Dr. Simpson accepted a new professional opportunity at the Cincinnati Children's Hospital Medical Center. Dr. Jack Hutto, Vice President of Quality Improvement and Outcomes at All Children's Hospital, now directs the Outcomes Core and supervise the core projects and activities. Dr. Hutto has been a member of All Children's professional medical staff since 1979, and has collaborated with Dr. Simpson on mutual outcomes projects.

PCRC Advisory Committee Leadership
The Advisory Committee Leadership for the PCRC project was comprised of two committees: an internal advisory committee and an external advisory committee. Each committee played a key role in the development and direction of the ACH Pediatric Clinical Research Center.

External Advisory Committee
The External Advisory Committee (EAC) was comprised of community-based leaders who had been active in community health organizations and national recognized leaders in maternal and child health research.

The committee included:

- Warren Andiman, MD, Professor of Pediatrics, Epidemiology and Public Health, Center for Institutional Research on Aids, Yale –New Haven Hospital
- Peter Gorski, MD, MPA, Professor and Director, Lawton & Rhea Chiles Center for Healthy Mothers and Babies, University of South Florida
- James M. Perrin, MD, MPH, Professor of Pediatrics, Director, Center for Child and Adolescent Health Policy, Massachusetts General Hospital
- Mrs. Thelma Rothman, former Chair of the all Children's Health System Board and founder of the All Children's Hospital Foundation Board., President of Kane's Furniture
- Desmond Schatz, MD, Professor and Associate Chair, Dept. of Pediatrics, Division of Endocrinology, University of Florida
- Elizabeth A. Shenkman, PhD, RN, Director, Institute for Child Health Policy, Associate Professor, Dept. of Pediatrics and Dept. of Health Policy and Epidemiology, University of Florida
- Dr. Phyllis Sloyer, Division Director, Children's Medical Services, Florida Department of Health
- Peter Wallace, Attorney, St. Petersburg, Florida

- Ayakao Watkins, MSPA, Director of Community Development and Partnerships for the Center for Health Equity, St. Petersburg, Florida

This committee was extremely helpful in the demonstration grant phase of the PCRC, bringing perspectives from institutions with well established research infrastructures and services. It advised our leadership and our Principal Investigator on grant development and program management, research agenda development and junior faculty recruitment. The EAC met twice a year for the first two years of the grant period. Unfortunately, the busy professional schedules of the individuals on the committee made it difficult to coordinate meeting dates where a quorum could be present. By the third year of the grant project period, it was decided to move away from a group meeting to an individual contact mode. Dr. Sleasman, our Program Director, and Dr. Simpson and Dr. Litman, our Associate Program Directors, were in frequent contact with members of the External Advisory Committee.

Internal Advisory Committee

The role of the Internal Advisory Committee for the PCRC was to provide comprehensive guidance to the direction and administration of the PCRC, and establish the priorities of the research to be conducted or supported, anticipating future needs for clinical and outcome research within the All Children's Hospital research community and proposing new initiatives. The Advisory Committee made recommendations to the All Children's Administration related to projects requesting PCRC support, recommended policies and reviewed operations to ensure that resources were used to advance the research mission of All Children's Hospital and the goals of the PCRC.

The Advisory Committee consisted of 6-10 members representing a cross-section of All Children's Hospital and University of South Florida Health Sciences Center pediatric faculty who were familiar with the broad elements of clinical and health outcomes research activities, currently had extramural research funding or had a history of such funding, and were familiar with the NIH scientific review process. The members were appointed on a rotating basis by the Principal Investigator who is the President of the All Children's Health System. The committee met monthly through the grant project period, and continues to meet.

IV. Continued Research Enterprise Development

In the 2006, the third year of the grant project period, we requested and received permission to further develop the ACH research enterprise by drawing together other ACH organizational units involved in direct clinical research services or integral to the research administration process. This institutional change was meant to enhance collaboration and increase the efficiency of the larger research enterprise, as well as serve as a magnet to investigators. These units included: the Cancer Oncology Group (COG); the Research Analyst for the Vermont Oxford Network; the Coordinator of the Institutional Review Board and the IRB Administrative Research Coordinator; the Medical Director for Blood & Bone Marrow Research; and the Research Pharmacist

Members of these units have been involved in collaborative projects benefiting the research enterprise as a whole, such the initialization and testing of modules for the **iRIS** (Integrated Research Information System) software solution.

As the Hospital moves forward with the strategic planning for research, this core will serve as the platform for the strategic expansion of pediatric research capacity in the future

V. Research Program Development

The PCRC pursued an aggressive dual strategy to encourage the development of research projects in the clinical and research programs of Neonatology, Immunodeficiency, Infectious Diseases, Cardiovascular Disease, Clinical Genetics, and Health Policy. The first strategy was through the sponsorship of small pilot grants of up to $20,000 for one year to USF and ACH investigators that needed additional preliminary studies prior to the submission of projects for extramural funding. The second strategy was for larger awards of up to $150,000 to programs with experienced principal investigators to establish new, or enhance existing, interdisciplinary pediatric clinical research programs at All Children's Hospital.

A total of sixty protocols received PCRC resources during the demonstration grant period, including thirty-two pilot projects and four program development awards. These projects represented the areas of endocrinology, public health, allergy and immunology, infectious diseases, HIV, perinatal cardiology, clinical genetics, oncology, and neonatology. They bring together NIH and NSF funded investigators from the Moffitt Cancer Institute and the University of South Florida, and All Children's Hospital. A list of these supported projects is included as Appendix 1.

In addition to the successes of our Research Program Development initiative, the PCRC has made significant progress in becoming a principal in the larger research enterprises of All Children's Hospital and the Department of Pediatrics at the University of South Florida. We are supporting several NIH-funded programs including the re-competition of the NICHD funded Adolescent Trials Network under the direction of Dr. Patricia Emmanuel, the Adolescent Medicine Leadership Group, a new RO1 entitled *Role of HIV-1 Envelope Diversity in Cellular Tropism*, and a recently submitted RO1 entitled *Impact of HIV-1 Genotype on Therapy Response in Children* both under the direction of Dr. John Sleasman. The PCRC is also providing support to the research efforts of the All Children's Hospital's Bone Marrow Transplantation Program under the direction of Dr. Michael Nieder, and the Children's Oncology Group under the leadership of Dr. Jerry Barbosa.

VI. Researcher Education and Career Development

In 2002 and 2003 respectively, both the National Institutes of Health (NIH) and the Institute of Medicine recognized that one of the barriers to the efficient movement of new scientific discoveries from the bench to the bedside was the shortage of qualified investigators. Early in the building process of the PCRC, we realized that there was a shortage of consistent educational opportunities for clinician-researchers wanting to develop their research skills and opportunities for clinical and translational research. As part of our efforts to enhance research training and

career development, the PCRC supported professional development opportunities through sponsorship of symposiums/conferences and monthly seminars.

Specifically, sponsorship support was provided to each of the following symposiums/conferences. PCRC-supported principal investigators were involved in organizing and presenting at these forums.

- Current Controversies in Lyme Disease (January 28, 2006)
- National Meeting on Child Health Information Systems (March 15-16, 2006)
- National Initiative on Children's Healthcare Quality (March 16-18, 2006)
- 13th Annual Weinstein Cardiovascular Development Conference (May 11-13, 2006)
- Perspectives in Immunology, Robert A. Good Immunology Symposium (June 9-12, 2006)

The monthly PCRC sponsored Research Seminar Series continues to provide a forum for sharing on-going and completed clinically related research. The attendance numbers are consistently between forty to fifty people including Hospital staff, USF residents, fellows and house staff. We are also pleased that the speaker list now includes PCRC-supported investigators (Appendix 2). The Seminar Series has also included research education topics such as human subject protection and writing for publication. The ACH Research Seminar Series will continue to be supported by the PCRC after the demonstration grant period as part of our professional development efforts for researchers

VII. Academic Output

We are pleased with the significant level of accomplishment and academic output reported by PCRC supported principal investigators thus far. This includes twenty-four peer reviewed articles, twenty-five abstracts, forty-two presentations, three book chapters, six posters, and over a million dollars in new funded projects. We anticipate continued academic activity in the future from the projects just completing data collection and analysis. A list of the all the reported academic output is included as Appendix 3.

In addition, we are also pleased to note that during the grant award period, the ranking of the USF Department of Pediatrics for total NIH award dollars rose from 51st in 2003 to 3rd in 2005. These dollars included awards received by principal investigators who received PCRC infrastructure or pilot grant support for research in pediatric immunology, infectious disease and molecular genetics.

VIII. Summary

The overarching goal of the PCRC demonstration project was to establish an administrative infrastructure to coordinate and co-locate the resources and personnel for pediatric clinical research at All Children's Hospital. With the support of this grant, we developed and implemented the foundation of a robust research infrastructure including state-of-the-art biomedical research equipment, advanced informatics technology equipment and information systems, and qualified personnel.

As we look to the future, there is a bolder vision for the ACH research enterprise precipitated by a number of factors including:

- The dissolution of the General Clinical Research Center Program by the NIH and integration of those resources into the more comprehensive Institutional Clinical and Translational Science Award (CTSA) program.
- The call by the NIH for the enhancement of the scientific talent pool and creation of new institutional models to increase the efficiency and speed of clinical and translational research.
- The receipt of a CTSA planning grant award by our USF partners
- The Completion of a new Hospital building in 2009 with expanded and technologically advanced clinical facilities

The PCRC is also proposing a "jumpstart" model to enhance the scientific research productivity of core clinical programs by attaching a professional research position to the core clinical program to coordinate research activities and ensure the efficient utilization of research resources. We believe that this will assist career clinicians in enhancing their clinical research skills and streamline the implementation and conduct of study activities. This research person will be located within the PCRC to facilitate collaboration and access to established PCRC research resources.

Clearly, without the support of this grant, we would not have been able to create the Pediatric Clinical Research Center or to move forward with the goal of creating a comprehensive clinical research program at ACH. In 2003, there was no formal research infrastructure in the ACH research community which could adequately support translational and clinical research. Now there is the foundation of a robust research infrastructure including state-of-the-art biomedical research equipment, advanced informatics technology equipment and information systems, and qualified personnel. We have quantifiably increased the number and quality of clinical, translational and health outcomes research projects occurring at All Children's Hospital and USF Department of Pediatrics. We are continuing the evolution of the All Children's research enterprise as All Children's Hospital and the University of South Florida Health Sciences Center continue dynamic periods of planning and growth. We anticipate that this advancement of rigorous pediatric research will eventuate in the better outcomes for infants, children and adolescents affected with a variety of congenital and acquired acute and chronic illnesses in Florida and nationally

Appendix 1

PROTOCOL LIST

Investigators	Protocol Title	Area
Tiffany Chenneville, PhD	Competence to Participate in Medical Treatment among Children with HIV	HIV/Health Services
Robyn Cheung, PhD Lisa Simpson, MD	Exploring the Volume/Outcome Relationship for Pediatric Cardiac Surgery in Florida Hospitals, 2000 to 2002: Would further regionalization improve outcomes?	Child Health Outcomes
David Cooper, MD	Retrospective study on the impact of Natrecor on patient blood pressure, serum sodium and creatine.	Critical Care
Noorbibi Day-Good, PhD Dareen Siri, MD	The Significance of Mannose-binding Lectin Levels in a Pediatric Immunodeficiency Clinic Population Using Available Laboratory Data	Immunology
Frank Diamond, MD	Adiponectin levels and the leptin/adiponectin ratio in infancy	Endocrinology
Morna Dorsey, MD	Pathogenesis of Asthma and Atopic Disease	Allergy & Immunology
Juan Dumois, MD	MRSA Surveillance Screening in the NICU	Infectious Diseases
Patricia Emmanuel, MD	ATN 056 PK of once daily antiretroviral therapy regimens containing Tenofovir and Atazana/Ritonavir in adolescents and young adults with HIV infection	HIV/Immunology
Patricia Emmanuel, MD	PACTG P1045, PACTG P1059, PACTG P1038	HIV/Immunology
Michael Gallant, MD	A Comprehensive Interdisciplinary On-line Database for Outcome Assessment in Cleft Lip and Palate	Maxi facial Surgery
Mark Glaum, MD, PhD	Identification of inflammatory gene expression profiles in nasal polyp tissue from children with cystic fibrosis	Immunology
Bethany Harmon	Parental Learning Styles	Hematology/Oncology
Thomas Havranek, MD/Roberto Sosa, MD	Feeding Very Low Birth Weight Infants with Umbilical Artery Catheters – A Randomized Clinical Trial	Neonatology
Thomas Havranek, MD	The Identification of Factors that Impact Maturation of Intestinal Blood Flow in Very Low Birth Weight Infants	Neonatology
Don Hilbelink, PhD	Finite Element Modeling of Normal Pediatric Heart Growth and Development	Anatomy
James Huhta, MD	Fetal Heart Screening Training Program	Perinatal Cardiology
James Huhta, MD	Folic Acid and Congenital Heart Disease: translational study	Perinatal Cardiology
James Huhta, MD	Folic Acid and Congenital Heart Disease: clinical study	Perinatal Cardiology
Jack Hutto, MD	Detecting Infections Associated With Health Care and The Prevention of These Infections	Health Care Quality

Patricia Kuster, PhD	Stress in Mothers of Technology-Dependent Children with Respiratory Support	MCH/Public Health
Jean Lee, PhD	Childhood Injury-Related Healthcare in Florida	Child Health Outcomes
Jean Lee, PhD	Children with Chronic Illness: a needs assessment for Camp Boggy Creek	Child Health Outcomes
Jean Lee, PhD/Lisa Simpson, MD	Hospital Care for Childhood Injury in Florida	Child Health Outcomes
Jean Lee, PhD	Variations in Pediatric Gastroenteritis Hospitalizations Among Florida Counties, 1993-2002	Health Outcomes & Quality
Melissa Loscalzo, MD	Prospective Analysis of Families with Left Outflow Tract Disorders	Clinical Genetics
Melissa Loscalzo, MD	Molecular Investigation of Chromosome Anomalies Associated with Specific Phenotypes	Clinical Genetics
Jorge Lujan-Zilberman, MD	PACTG-P1052	HIV/Immunology
Robert Nickeson, MD	Macrophage Responses to Joint-Specific Stimuli: Development of a Novel Molecular Classification Scheme for JRA/JIA	Immunology
Denise Maguire, PhD	Efficacy and Risk of ChloraPrep® in Infants	Neonatology/ Nursing Research
Shyam Mohapatra, PhD	Role of Natriuretic Peptide-Cascade in the Genesis and Control of Asthma	Internal Medicine Immunology
James Mulé, MD	A pilot study of high dose chemotherapy and autologous stem cell transplant followed by tumor-pulsed dendritic cell vaccination for children with newly diagnosed metastatic Ewing Sarcoma family of tumors.	Oncology/ Moffitt
Michael Nieder, MD	Long Term Outcomes of Hurler Patients	Hematology/Oncology
Michael Nieder, MD	Phase I/II trial of De-escalation of Busulfan with Fludarabine and Antithymocyte Globulin as Preparative Therapy for Hematopoietic Stem Cell Transplant for the Treatment of Severe Congenital T-cell Immundeficiency	Hematology/Oncology
Michael Nieder, MD	A Phase II Study of Pentostatin for the treatment of high risk or refractory chronic GVHD in children	Hematology/Oncology
Mary Pavan, MD	Evidence-Based Developmental Screening: A Pilot Quality Improvement Project	Child Development & Graduate Medical Education
L. Pedroza-Martins, PhD	Impact of HIV Genotype of Therapy Response in Children	HIV/Immunology
Aleksandra Petrovic, MD	T Cell homing in intestinal graft versus host disease	Immunology/Oncology
Aleksandra Petrovic, MD	Feasibility study of chimerism testing following allogeneic transplant	Immunology/Oncology
Etienne Pracht, PhD	Are pediatric trauma victims better off when treated in designated trauma centers?	Health Quality & Outcomes

Henry Shapiro, MD	Developmental-Behavioral Pediatrics Informatics Workgroup	Developmental-Behavioral Pediatrics
Darlene Shearer, PhD	Web based Clinical Research Learning Modules	Research Education
Wendy Struchen Shellhorn, ABD	Maternal Interaction Style, Reported Experiences of Care and Pediatric Health Care Utilization	Public Health
Lisa Simpson, MD/Donna Ettel, PhD	An Analysis of Information Technology Capacity and Adoption Intentions Among Child Health Providers in Florida	Child Health Outcomes
Lisa Simpson, MD	The Impact of State Medicaid Policy on Pediatric Patient Safety in Hospitals	Child Health Outcomes
Lisa Simpson, MD	Health Care for Children and Youth in the United States: Annual Report on patterns of Coverage, Utilization, Quality, and Expenditures by Urban/Rural Status	Child Health Outcomes
Lisa Simpson, MD	A Quality Chart book for Florida's Children	Child Health Outcomes
Lisa Simpson, MD	Information Technology and Quality Applications in Hospitals Serving Children	Child Health Outcomes
John Sleasman, MD	Analysis of Lymphocytes from Normal Blood Donors	Immunology
John Sleasman, MD	Biological Effects of HIV-1 Genetic Variability Project #1 HIV Variants within PBMC Subpopulation in Infants	HIV/Immunology
John Sleasman, MD	Measures of the magnitude and breadth of the T-cell receptor variable beta response to influenza recall antigen in bone marrow transplant patients compared to healthy controls	Immunology
John Sleasman, MD Rima Sanka, MD Jayna Doshi, MD	The Effect of Exposure to Red Tide Toxin on Nasal Cytokine Production	Immunology
John Sleasman, MD	Role of HIV-1 Envelope (ENV) Diversity in Cellular Tropism	HIV/Immunology
Shannon Suldo, PhD	Dual-Factor Model of Mental Health in Youth: Prediction of Physical Health, Educational and Social Outcomes	Health Services
Kathy Swan, RN	Urinary Proteins as an Early Indicator of Effect of Hydronephrosis on Renal Function	Nephrology
Janet Sullivan, PhD	A Patient Education Module for Prevent of Perinatal Transmission of HIV	Infectious Disease/Public Health
Susan Vadaparmpil, PhD/Gwendolyn Quinn, PhD	Barriers to Fertility Preservation Among Florida Pediatric Oncologists	Oncology/Moffit
Catherine Walsh, PhD	Effect of brevetoxin on human immune cells	Immunology/ Public Health
Jake Zieders, MD	Retrospective study on ear tube insertion and adenotogy and need for future surgical interventions	Otolaryngology

Appendix 2

ACH RESEARCH SEMINAR SERIES

2005-06

September 2005	Advances in Treatment for Graft versus Host Disease Dr. Michael Nieder
October 2005	Cancelled due to Hurricane Wilma
November 2005	Twists and Bends of Cardiac Looping Dr. Kersti Linask
January 2006	The Lectin-Complement Pathway (MBL) and its Role in Innate Immunity Noorbibi Day-Good
February 2006	MRSA Surveillance Screening in the NICU Dr. Juan Dumois
March 2006	A Clinical Cancer Vaccine Approach for Pediatric Solid Tumors Dr. Jim Mule
April 2006	Validation of fetal CV profile score Dr. James Huhta
May 2006	Microencapsulation for Immunoprotection of Pancreatic Islet Cell Grafts in the Therapy of Type 1 Diabetes Mellitus Dr. Riccardo Califiore
July 2006	The paradox immune reconstitution despite viral replication in HIV infected children Dr. Carina Rodriguez
August 2006	The ACH Clinical Research Enterprise Mr. Sandy Wismer

2006-07

September 2006	Manipulation of the T cell Response to Minor Histocompatibility Antigens in Hematopoietic Cell Transplantation -New Strategies to Separate the GVL Effect From GVHD Dr. Marie Bleakley
October 2006	Do Pediatric Trauma Victims in Florida Have Reduced Mortality Rates When Treated in Designated Trauma Centers? Dr. Etienne Pracht

November 2006	The Power of CGH Microarray Analysis: Cytogenetics in the 21st Century Dr. Maxine Sutcliff
January 2007	Writing for Publication Dr. Jane Carver
February 2007	eResearch at All Children's Tana LeRoux
March 2007	Competence to Participate in Medical Treatment Among Children with HIV Dr. Tiffany Chenneville
April 2007	Addressing the Adolescent HIV Epidemic Through a Comprehensive Research Agenda Dr. Patricia Emmanuel
June 2007	Medical Library Resources: A World of Information at a Researcher's Fingertips Patricia Clark, MLS

Appendix 3

ACADEMIC OUTPUT

BOOK CHAPTERS

1. Sleasman JW, Virella G. AIDS and Other Acquired Immunodeficiency Diseases. In: Medical Immunology, 6th Edition (G.Virella, ed.) Informa Healthcare, New York, NY, pp 429-451, 2007

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ABSTRACTS

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PRESENTATIONS

1. Kamchaisatian W, Haraguchi S, Day NK, Sleasman JW, Tangsinmankong N. Chemokine receptors (CXCR4) and CCR5) response to bacterial superantigen on $CD4^+$ T lymphocytes and $CD14^+$ monocytes. Lewis Barness Fellows' Forum, St. Petersburg, FL, April 15, 2004.

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10. Chenneville T. Competence to participate in medical treatment among children with HIV: Preliminary Findings. USF School Psychology Program Research Colloqium Series, December 2005.

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12 Thomas B, Hilbelink D, Saigal S. Wavelet Analysis of Heart Geometry for Morphological Modeling. Medicine Meets Virtual Reality, Long Beach, California, January 2006.

13. Sleasman, J. The Taming of HIV in Children and Adolescents. Silver Award for Excellence in Pediatric AIDS Research. Children's Hospital of Philadelphia, Philadelphia, PA. February 21, 2006

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30. Suldo S. Dual-Factor Model of Mental Health in Youth: Group Differences in Physical Health, Educational, and Social Functioning. International Positive Psychology Summit (IPPS), October 5 – 7, 2006, Washington, DC.

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POSTERS

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2. Simpson L, Ettel D, Menachemi N. Office Based Applications Supporting Quality of Care. AcademyHealth, June 25-27, 2006, Seattle, Washington. (Poster)

3. Struchen-Shellhorn W. How can WIC and Home Visitation Programs Help to Improve Pediatric Health Care Utilization Patterns? 2006 National Association of County and City Health Officials. July 26-28, 2006, San Antonio, Texas.(Poster)

4. Struchen-Shellhorn W, Simpson L, Menachemi N. Which Child Health Providers and Provider Offices are the First to Adopt the Use of Electronic Health Records and Why? Florida Public Health Association, August 2006, West Palm Beach, Florida (Poster)

5. Lee J, Cheung R, Liller K, Pracht E, Langland-Orban BL, Simpson L. Inpatient Deaths During Childhood Injury-Related Hospitalizations: Trends and Variations by Payer Status, Florida 1998-2002 2006 Pediatric Academic Society Meeting, April 29-May 2, 2006, San Francisco California. (Poster)

6. Struchen-Shellhorn W, Perrin K, Simpson L, Kromrey J, Mahan C, Graven S. The Role of Mothers in Accessing Medicaid-Funded Well Child Care and Immunizations. 5th Annual Florida Medicaid Research Conference, 2006: Patient Empowerment and Health Literacy. June 1-2, 2006, Tallahassee, Florida.(Poster)

THESIS/DISSERTATIONS

Shaffer, E. J. (2006). *An investigation of a dual-factor model of mental health and related physical health outcomes among early adolescents*. Unpublished Master's Thesis, University of South Florida, Tampa, Florida.

Shellhorn, W. (2006) *Maternal Interaction Style, Reported Experiences of Care and Pediatric Health Care Utilization* Unpublished Doctoral Dissertation, University of South Florida, Tampa, Florida.

GRANTS FUNDED

2 R01 AI47723-04A1 Sleasman PI 02/15/06 – 1/31/11
NIH/NIAD $300,000
Impact of HIV-1 Genotype on Therapy Response in Children
The major goals for this project are to determine structure-function relationships between HIV-1protease and $p7^{NC}$ in children treated with combination therapies that include protease inhibitors.

R01 AI065265-01 Goodenow PI; JW Sleasman Co-PI 04/01/05 – 03/31/10
NIH/NICHD $355,370
Role of HIV-1 Envelope Diversity in Cellular Tropism
The goal of this research is to determine the interactions between HIV-1 envelope and CD4 target cells and consequence of viral evolution on cell tropism in HIV-infected children and adolescents

GC04-794 – OHHI 2005
National Oceanic and Atmospheric Administration Walsh PI; Sleasman Co-PI
10/01/05 – 09/30/08
Effects of brevetoxin exposure on human immune cells $303,305
The overall objective of this project is to understand mechanisms of immunotoxicity resulting from brevetoxin exposure

American Heart Association
Suncoast Cardiovascular Steele PI 07/01/07 – 06/30/08
Research and Education Foundation $15,000
The Atrial Appendage as a Source of Cardiac Stem/Progenitor Cells

AHA 0755331B
American Heart Association Steele PI 07/01/07 – 06/30/10
Cardiac Injury: Transplantation Strategies for Immediate and Sustained Repair $264,000