

Director's Welcome Message

We had a wonderful response to our first issue of Making the Grant Rounds. Thanks for your comments and suggestions for future editions. We appreciate your feedback and value the trust you place in us as your partners in grant stewardship.

This is an exciting time for Connecticut Children's and OGSP. We were successful in receiving outstanding results from our annual A133 audit. This year there were no deficiencies reported. This is a true testament to the dedication of the staff of OGSP, Finance and Accounting and their commitment to the work that they perform to ensure compliance.

Another reason to celebrate

is that Drs. Christine Finck, Jeffrey Hyams and Juan Salazar have received notification that their National Institute of Health (NIH) research proposals are being funded.

Christine Finck received 2 NIH awards. Dr. Finck's research seeks to develop new ways to improve lung function in premature or diseased neonates, using a mouse model. The goal of this work is to alleviate neonatal hypertension using stem cell therapy to augment premature damaged lung tissue with in vitro stem cell derived distal airway cells. Her R01 proposal was funded in July and a RC4 proposal with the University of Vermont received a very favorable score

and was funded in September.

Dr. Jeffrey Hyams, with his co-investigators Drs. Ted Denson and MioK Kim at Cincinnati Children's, has assembled a group of top scientists in the US and Canada to study new approaches to therapy for children with ulcerative colitis. Their proposal for a 1-2 year planning grant was funded and will likely lead to a 5 year U01 multicenter trial, funded by the NIH.

Dr. Juan Salazar conducts translational research on host innate and adaptive immune response to spirochetal agents, primarily the bacterium *Borrelia burgdorferi*, causal agent of Lyme Disease. His R01 proposal has resulted in an award of 1 year "bridge"

funding, placing him in a very favorable position for full funding. He submitted the proposal for the full R01 in November. We will know if this new grant will be funded sometime in April 2011.

This is a major accomplishment for the each of the Investigators and Connecticut Children's. Please join me in congratulating these Investigators for their hard work.

In this issue...

- We take a look at the PIs whose clinical trial studies opened
- Highlight the grants of Drs. Dworkin and Parikh
- Provide a useful Q&A section

-Until next time, Lisa Benson

W. K. Kellogg Foundation Awards \$2.4 Million Grant to Connecticut Children's Medical Center for Continued Expansion of the *Help Me Grow* Program

Young children across the country with developmental and behavioral issues will have better access to a new model of care and service coordination thanks to a generous \$2.4 million grant awarded to Connecticut Children's Medical Center by the W.K. Kellogg Foundation of Battle Creek, Michigan.

The three-year Kellogg grant will fund replication of the Connecticut *Help Me Grow* program (HMG) in ten states across the country. Connecticut HMG is an innovative system that provides a cost-effective, efficient, and user-friendly



Dr. Paul Dworkin, Project Director; Joanna Bogin, Program Manager; Sara Sibley, Administrative Coordinator; TA Consultation Team: Marijane Carey, Kareena Duplessis, Amy Fine, Rebecca Hernandez, Lisa Honigfeld and Tanika Simpson. Not in this picture: Elsa Jones, Program Administrator and Marcia Hughes, TA Consultant.

mechanism for identifying children from birth to the age of eight for developmental or behavioral problems and connects them through a single

point-of-entry, to appropriate community resources in a timely manner. One telephone call initiates a process in which children are screened, assessed

and linked to a program or service that meets their needs.

"We are extremely grateful to the W.K. Kellogg Foundation

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Shipping of Research Specimens

When shipping or transporting research specimens, one should ask the following questions:

- Who will be shipping the specimen?
- Will the specimen be transported in a personal vehicle?
- How will the specimen be packaged?
- Do you have all the proper packaging material?
- Do you need to be certified to package and ship specimens?

If the specimens are going to be shipped by the patient, please provide the following:

- Instructions on how to properly package the specimen
- A completed shipping label
- Packaging material

If the specimens are going to be transported to and from a destination by a member of the research team:

- Package the specimen properly
- You can only drive from Point A to Point B

Please direct questions or concerns to Kim Jennings in Research Compliance

There are rules and regulations that need to be followed for shipping and transporting of hazardous materials. Per the Collaborative Research Agreement between Connecticut Children's and the University of Connecticut Health Center, "the transportation of biological specimens, tissues, hazardous chemicals, radioactive materials and other materials regulated by the United States Department of Transportation, the Environmental Protection Agency, the Nuclear Regulatory Commission or other regulatory agencies must be pre-approved by the UCHC Office of Research Safety." (Please also see the Shipping and Receiving of Dangerous Goods Policy in the Environment Care Department or call Mike Tortora for further information).

W. K. Kellogg Foundation Awards \$2.4 Million Grant to Connecticut Children's Medical Center for Continued Expansion of the *Help Me Grow* Program, *continued from page 1*

for their generous support of this vital program," said Paul Dworkin, MD, Connecticut Children's physician-in-chief. Nationwide, it is estimated that approximately 12-16 percent of children experience developmental, behavioral and/or emotional disorders. "Experts agree that early detection of at-risk children offers the best hope for optimal long-term outcomes. But connecting children to these services often proves difficult and requires knowledge of programs and eligibility requirements and persistence in overcoming barriers. The *Help Me Grow* program helps states provide the necessary components for a comprehensive system of early detection and referral of at-risk children."

The Kellogg Foundation Grant will support the replication of HMG in 10 states over the next three years. The grant will also enable a technical assistance team to continue to support five states in their current efforts to expand their regional HMG replication efforts statewide. Dr. Dworkin said another key component of the Kellogg Foundation grant is the creation of a National Technical Assistance Center.

"The National Technical Assistance Center will provide consultation, research, policy analysis and development, and evaluation of HMG," Dr. Dworkin said. "The sites will be supported by a database designed to collect such process measures as the numbers and types of calls, rates of developmental screening and surveillance, and parent and child health provider satisfaction."

Through Dr. Dworkin's efforts, HMG began in the summer of 2001 as a statewide expansion of Hartford's ChildServ program which addressed concerns about children's

health and development. The State of Connecticut's Children's Trust fund administers the program with care coordinators who train parents, pediatric and other providers to recognize the early signs of developmental problems and to contact HMG with concerns. The staff also research community-based resources and coordinate networking opportunities for human services providers. Additionally, the Trust Fund contracts with the United Way/211 to operate Child Development Infoline, which identifies needed services, provides referrals and follows up with families to ensure that each child is successfully connected.

Successful outcomes through HMG – families who are successfully connected to a service – have grown and remain impressively high. Eighty percent of service needs were addressed through HMG during the 2007-2008 year. But Dr. Dworkin stressed that these figures do not illuminate all the efforts of the Child Development Infoline care coordinators and families who are typically confronted with gaps and barriers to services. Persistent follow through and a great deal of problem solving enable care coordinators to eventually link families to needed services.

National replication of HMG will increase awareness and understanding of the importance of early identification and intervention for at-risk children among parents, clinicians, policy makers and the public. Dr. Dworkin said that he is proud of the fact that HMG first started in Hartford, expanded throughout Connecticut and has since been replicated across the country. HMG was first replicated in Orange County, California, through the

CA First Five Program, with Polk County, Iowa following soon after. Earlier support from another major foundation, The Commonwealth Fund of New York City, has enabled HMG to be replicated in South Carolina, Kentucky, New York, Oregon and Colorado.

"By conclusion of the Kellogg Foundation grant period, we anticipate the development of comprehensive state HMG programs in 18 states, thereby achieving a 'tipping point' to sustain national replication activities to ultimately reach the entire nation," Dr. Dworkin said.

Joanna Bogin, MS, is the program manager for the national dissemination of HMG, and said that many states have some of the necessary components for a comprehensive system of early detection and referral of at-risk children, but few have a system that is as integrated and effective as HMG.

"Over the past nine years, HMG has not only successfully identified at-risk children, but also has successfully linked them to services," Bogin said. "Through promoting partnerships among community resources, funding sources and state agencies, HMG also has demonstrated that public-private collaborations can enhance capacity and minimize costs."

Established in 1930, the W.K. Kellogg Foundation supports children, families and communities as they strengthen and create conditions that propel vulnerable children to achieve success as individuals and as contributors to the larger community and society. Grants are concentrated in the United States, Latin America and the Caribbean, and southern Africa. For further information, please visit the Foundation's website at www.wkcf.org.

Question and Answer Section

Q: What goes on in the Office of Grants and Sponsored Programs? Exactly, what kind of work do you do?

A: The Office of Grants and Sponsored Programs uses a “cradle to grave” award lifecycle approach to provide all aspects of award administration:

- We stay on top of regulatory issues (e.g. Office of Management and Budget Circulars, Federal Acquisition Regulations etc.)
- We provide budget and proposal development, preparation, review, institutional authorization and submission services
- We assist with compliance issues (human & laboratory animal use, certifications, other regulatory requirements)
- We review and negotiate each grant award and project initiation
- We oversee funded programs (management systems, agency liaison, accounting, fiscal and reporting issues)
- We provide direction in the closeout process (final reporting, audit issues, project conclusion)

Q: What are the basic elements of a proposal?

A: Most agencies specify proposal forms or formats and provide clear guidance about content and format, including requirements for page limitations copies. These instructions must be followed to the letter. In general, proposals contain the following elements:

- Cover page (usually a pre-printed form or created by the Department)
- Abstract or Project Summary
- Table of Contents
- Project Description
- Budget and Budget Justification
- Biographical Sketch (for key personnel)
- Resources (Equipment and Facilities)
- References
- Appendices
- Certifications or other forms

Please contact the OGSP to determine exact guidelines and submission requirements of an agency or sponsor.

Q: What happens after an individual receives an award notice for a new grant?

A: For every new grant received, the OGSP will set up an official project start up or post-grant award meeting. At this session, we will review the following details with the Principal Investigator/Project Director:

- Roles and responsibilities of staff
- Specific “next steps” and timelines for project implementation and planned activities
- Grant requirements of the funding agency
- Suggested systems for record keeping
- Personnel hiring processes
- Time and effort certifications, if applicable
- Issues, policies and procedures pertaining to equipment and supply purchases and consultant subcontracting, if applicable
- Reporting requirements and report due dates
- Any other issues of concern

Q: What is a sponsored program?

A: A plan or project that is funded by an external entity through an award. Sponsored programs include research, instruction and other subsidized activities.

Q: What is a budget?

A: A budget is a financial expression of the proposed scope of work to be completed. It is also a guiding document for conducting work when awarded. *Criteria of a good budget:*

- *Translates resource needs to dollars*
- *Confirms to agency guidelines*
- *Realistic estimates*
- *Supports the program*
- *Clearly justified or explained*
- *Plans ahead and includes projections for the full award period*

Q: Why does the OGSP review grant expenditures (for salary and non-salary items) on a regular basis?

A: It's important to ensure that charges that post to sponsored accounts are correct and appropriate. Understanding and adhering to award and policy requirements and ongoing account monitoring improves the quality of our financial reporting, encourages compliance with regulatory conditions and reduces the administrative burden of cost overruns or unexpended balances at the end of a grant term. We evaluate expenditures to determine that they are reasonable, allowable, allocable, and consistently applied to a grant funded project.

Q: What is the role of a Departmental Grants Administrator in the OGSP office?

A: Departmental Grants Administrators are assigned to a specific group of faculty to manage their grant portfolios as a whole. Departmental Grant Administrators meet with assigned Principal Investigators/Project Directors (PI/PDs) on a regular basis to process transactions, review spending, offer projections and provide guidelines on the management of on-going awards. Departmental Grants Administrators partner with Central Administrators and serve as essential points of contact for (PI/PDs) and staff.

Q: Why do I have to route my grant-funded travel through the Grants Office?

A: The OGSP will review the grant and budget for allowability, allocability and availability of travel funds. We will provide travel pre-approval (if appropriate) and will supply needed signatures on the Travel Authorization Request Form. The Grants Office will process conference registration payments, make Egencia travel arrangements and process other requested transactions. If travel is booked to a grant without prior approval, the Grants Office cannot guarantee payment for the travel expenses. If it is determined that the grant cannot support the travel expenses, the PI/ PD will be responsible for securing the funding to pay for the travel expenses incurred. If you have questions on our policies and procedures, please contact Lisa Benson at 860.545.9967. For assistance with the Egencia Travel System, please contact Danielle Lopez at 860.545.9905.

Q: What's your best advice for management of a grant?

A: Communicate: Schedule meetings with the OGSP, ask questions, respond to mail / email / phone messages
Keep Up With the Budget: It's a competitive process for an academic medical center to apply for and receive grant money. The public or private funding agency elects to make an investment in our future. Connecticut Children's will be held accountable for the stewardship of its grant funds. Please set aside time each week to oversee your grants and review reports from the OGSP.

Meet All Reporting Deadlines: Grant reports must be filed by the due date –no later! Mark all due dates ahead of time on a calendar and remember that your narratives must be submitted to the OGSP for review or submission at least 5 days prior to the deadline. Complete reports as if you plan to apply for funding again. (You do, don't you?)

Q: What is the difference between a grant and a gift?

A: A "grant" is an award of financial assistance from a funding agency to carry out a public purpose of support, inspiration or stimulus. A grant involves a defined activity on a project such as the hire of new personnel, the purchase of program supplies or the development of a clinical study or research plan. At a minimum, the agency or provider requires Connecticut Children's to report on how the funds were spent and or what progress has been made in accomplishing the goals of the activity. In contrast, a "gift" made to Connecticut Children's involves a transfer of funds by the donor with no restrictions. The provider receives no direct benefit for the donation and requires nothing in exchange from us beyond a general assurance that the intent of the contribution will be honored (e.g. to improve the physical and emotional health of children). A gift allows us the freedom to manage a project and determine how the assets will be utilized. There are no required deliverables or reports on a gift. (Special note: The OGSP administers grant awards and the Foundation manages gifts and donation accounts.)

New Clinical Trials

Congratulations to the Principal Investigators (PIs) whose studies opened between January and September 2010.

Study Name	Sponsor	PI	Division
H1N1 – PALISI "Genetic Epidemiology of Life-Threatening Influenza infection in Children"	Massachusetts General	Dr. Christopher Carroll	Primary Intensive Care Unit
H1N1 Registry – PALISI "Treatment for Acute Lung Injury (ALI) and the Acute Respiratory Distress Syndrome (ARDS)"	Massachusetts General/NIH	Dr. Christopher Carroll	Primary Intensive Care Unit
"The Genetics of Severe Asthma in Children"	UConn Health Center – General Clinical Research Center (GCRC)	Dr. Christopher Carroll	Primary Intensive Care Unit
"Genetic Variations and Biomarkers in Children with Acute Lung Injury"	DHHS/NIH Medical College of Wisconsin	Dr. Allison Cowl	Primary Intensive Care Unit
"Sedation Management in Pediatric Patients with Acute Respiratory Failure" (RESTORE 2)	NHLBI/NINR	Dr. Allison Cowl	Primary Intensive Care Unit
"Studies to treat or Prevent Pediatric Type 2 Diabetes" (STOPP-T2D)	NKH-George Washington University	Dr. Elizabeth Estrada	Endocrinology
"Inhaled Nitric Oxide for the Prevention of Bronchopulmonary Dysplasia (BPD) in Preterm infants requiring Mechanical Ventilation or Positive Pressure support for Days 5-14 after Birth"	INO Therapeutics, LLC	Dr. James Hagadorn	Neonatology
"A Prospective, Multicenter, Open-label, Phase 3b Study of Human Plasma-Derived Factor XIII Concentrate in Subjects with Congenital Factor XIII Deficiency"	CSL Behring, LLC	Dr. Nate Hagstrom	Hematology/Oncology
"Rotarix Surveillance Activity for Gastroenteritis Among Infants <19 months of age" (ROTA)	NIH/ Yale Sub award	Dr. Melissa Held	Division of Hospitalist Care
"A Non Interventional Long-Term Post Marketing Registry of Patients treated with Cimzia for Crohn's Disease" (Secure Registry)	UCB Cell Tech – Schwarz Biosciences, Inc.	Dr. Jeff Hyams	Gastroenterology
"A Multidisciplinary Human Study on the Genetic, Environmental and Microbial Interactions that Cause Inflammatory Bowel Diseases" (GEM Study)	Mount Sinai Hospital – Canada (CCFA)	Dr. Jeff Hyams	Gastroenterology
"A Phase 2, Open Label, Multicenter Study of the Safety of Ritonavir-Boosted – for the treatment of HIV-1 Infected Subjects"	Gilead Sciences, Inc.	Dr. Juan Salazar	Infectious Disease
"A Randomized, Double-Blind, Placebo Controlled Study to Evaluate the Efficacy and Safety of Tocilizumab in patients with active Polyarticular Juvenile Idiopathic Arthritis"	Roche Pharmaceuticals	Dr. Lawrence Zemel	Rheumatology
"A 15 Week, Randomized, Double-Blind, Placebo-Controlled, Parellel Group Efficacy Study of Pregabalin in Adolescents (12-16 years) with Fibromyalgia"	Pfizer	Dr. Lawrence Zemel	Rheumatology
"Evaluation of Exagen Diagnostic Tests in Children with Inflammatory Bowel Disease and Irritable Bowel Syndrome: A Pilot Study"	Exagen Diagnostics	Dr. Jeff Hyams	Gastroenterology

New Research Funding Awarded in FY 2010:

Quarter	Dates	Total New Awards	Year 1
Q1	10/1/09 - 12/31/09	\$ 548,334.00	\$ 192,656.00
Q2	1/1/10 - 3/31/10	\$ -	\$ -
Q3	4/1/10 - 6/30/10	\$ 3,832,104.00	\$ 1,133,187
Q4	7/1/10 - 9/30/10	\$ 1,030,540.00	\$1,024,595.00
		\$ 5,410,978.00	\$2,350,438.00

Increase in Indirect Costs Received:

FY 2008	\$858,189
FY 2009	\$924,050
FY 2010	\$1,035,931

NIH Timeline: New Applications

Receipt Date	Scientific Review	Council Review	Award Date
February 5	July	October	December
June 5	October	January	April
October 5	March	May	July

For more information, please connect to <http://grants.nih.gov/grants/funding/submissionschedule.htm>.

Our Team

The Office of Grants and Sponsored Programs has grown to an impressive team of dedicated professionals to assist with your grant needs. Please contact a staff-member for support in the pre-award or post-award process of your quest for funding.

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NIH Update: Error Correction Window Elimination

Beginning with due dates on or after January 25, 2011, NIH, AHRQ and NIOSH will eliminate the error correction window from the application submission process. NIH will continue to make accommodations for Federal system issues that threaten or

prevent on-time submission of an individual application, if appropriately documented and verified by NIH support staff. Moreover, NIH still will determine and implement contingency plans on an as-needed basis for widespread system issues and natural

disasters. The elimination of the error correction window does not affect the two-business-day application viewing window. For more information, connect to <http://grants.nih.gov/grants/news.htm> and see NOT-OD-10-123.

NIH Issues Federal Funding Accountability and Transparency Act Notices (FFATA)

Effective 10/1/10, all NIH applicant and grantee organizations must have a Dun & Bradstreet Universal Numbering System number and maintain an active registration in the Central Contractor Registry database. Further, all grantees

must notify potential first-tier subrecipients that no entity may receive a first-tier subaward unless the entity has provided its DUNS number to the prime grantee. NIH also issued a notice containing a new term of award on Transparency

Act subaward and executive compensation reporting. In a third notice, NIH is revisiting all currently open funding opportunity announcements to include requirements relating to FFATA compliance. Link: http://grants.nih.gov/grants/public_accountability/ffata.htm

Highlighted Principal Investigator



Dr. Nehal S. Parikh is the Director of the Childhood Solid Tumor Program in the Hematology/Oncology division

here at Connecticut Children's. Dr. Parikh has developed a specialized expertise in the management of childhood solid tumor, with a particular research interest on advancing the care of children with neuroblastoma. Recently he has been invited to join a nationally recognized consortium that helps develop and bring forth novel therapies for children with advanced disease. His partnership with Neuroblastoma and

Medulloblastoma Translational Research Consortium (NMTRC) will provide novel therapeutic options for children with relapse or refractory Neuroblastoma and Medulloblastoma in our region. Neuroblastoma and Medulloblastoma are primarily pediatric cancers that affect over 1000 children a year. Dr. Parikh is a principal investigator for these phase 1 and 2 clinical trials. The initial clinical trials will be offered in late 2010/2011. He is also in the process of helping develop another novel approach that will help personalize therapies to target the individual patient's specific cancer genetic makeup.

Dr. Parikh has also been the lead physician charged with developing an international outreach program which will help advance the care of children with neuroblastoma in low-income countries. In partnership with St. Jude's Children's Research Hospital, he has developed a web based international platform for consultative discussion and education with physicians caring for children with challenging cases in pediatric cancers.

Many congratulations to Dr. Parikh and his team with these new initiatives to help children fight cancer in Connecticut and across the globe.

Have You Seen Us?

In addition to our traditional duties, the Office of Grants and Sponsored Programs staff participates in a number of extracurricular activities. In 2010, we were involved in the following events:

- 102.9 DRC FM Radiothon
- Adopt a Family

- Employee Picnic and Holiday Party
- Friends' Storybook Gala
- Gingerbread Decorating Contest
- Pumpkin Decorating Contest
- Professional Development Courses (through Connecticut Children's Medical Center, National

- Council of University Research Administrators, and the Society of Clinical Research Associates)
- Rewards and Recognition Committee
- United Way Day of Caring and Employee Campaign
- Vie for the Kids Barbeque
- And other programs and fund-raising initiatives

throughout Connecticut Children's Medical Center

In addition, our staff-members are active and involved in local community and faith-based organizations. Please get to know us and see us in action!