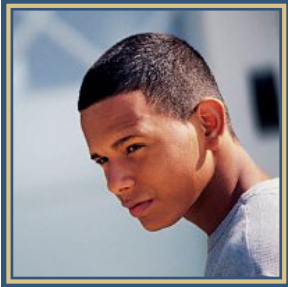


Special Interest



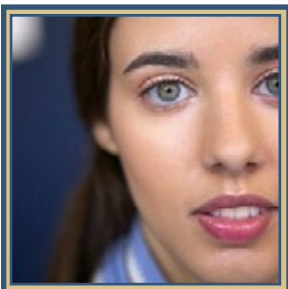
Elizabeth McCauley: A Research Pioneer in the Field of Adolescent Depression *Page 2*

Recent studies show that approximately 20 percent of adolescents will have at least one episode of clinical depression by age 18, and 65 percent will experience less severe, short-term symptoms of depression. Medical understanding of adolescent depression and suicide has increased dramatically over the last two decades, thanks in part to the efforts of Children's researcher, Dr. Elizabeth McCauley.



The Research and Family Liaison *Page 3*

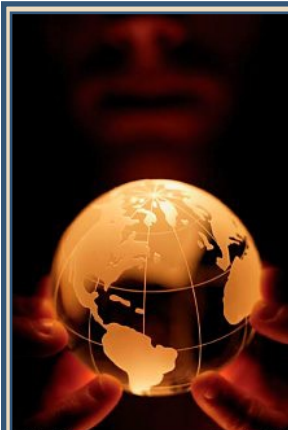
Children's Research Family Liaisons are investigating the challenges of consenting in the real world and looking for practical ways to improve the process for everyone. As part of the Research and Family Liaison (RFL) role development, Zuraya Aziz and Halle Showalter have been observing consent conferences to learn about the process at Children's.



Reconsenting at Age Eighteen *Page 4*

What happens if a child reaches the legal age of consent while enrolled in a study? According to the Office for Human Research Protections (OHRP), the subject's legally effective informed consent must be obtained.

Dr. Kristie Bjornson Brings Clinical and Outcomes Research Together *Page 6*



interaction Special Feature

Global Perspectives on Research at Children's: A 3-Part Series

The elimination of childhood disease is not bound by geography. The answers to research questions and previously undiscovered cures or therapies may be waiting in places far from the laboratories and clinics in Seattle, Washington. This series of articles will take a look at the work of Children's researchers whose work includes global partnerships, travel and discovery in the fight against the causes of childhood illness.

In this month's issue: Part 2 - Crossing the Divide: Building Research Resource Bridges to Ukraine *Page 5*

Research Events Calendar

**2006-07 THINK Seminar:
Clinical Research - Working
with the Media**

Friday, Dec. 5

Page 4

Grants.gov Training Seminar

Friday, Dec. 5

Page 14

Also in this issue...

2006-2007 THINK Seminar *Page 4*

Free, On-Site Vector NTI
Software Training Offered to
Researchers *Page 7*

Fellows Research Day *Page 7*

Introducing Victoria Cleator *Page 8*

Fed Ex Kinko's to IKON *Page 9*

Study Manager Update *Page 10*

Change in NIH Grant Deadlines *Page 11*

Grants.gov Training
Opportunity *Page 13*

Welcome to Research
at Children's! *Page 13*

Fifth Annual "Practical Aspects of
Conducting Pediatric Trials" *Page 14*

SPECIAL INTEREST

Elizabeth McCauley: A Research Pioneer in the Field of Adolescent Depression

Recent studies show that approximately 20 percent of adolescents will have at least one episode of clinical depression by age 18, and 65 percent will experience less severe, short-term symptoms of depression. Individuals diagnosed with depression as children are also more likely to have another depressive episode in their lifetime. The individual and social costs of these facts are evident. Depression can impede school and job performance, and it can hinder social adjustment over the long-term. Research suggests that adolescents with clinical depression may also be at greater risk for alcohol and drug abuse, suicide and other types of health problems.



Dr. Elizabeth McCauley

Given the importance of this issue, it may come as some surprise that as little as 20 years ago, many psychologists and physicians still believed that children were unable, both cognitively as well as emotionally, to experience depression. Thankfully, the situation has changed dramatically in the past two decades, thanks in large part to researchers such as **Elizabeth McCauley**, Associate Director, Child and Adolescent Psychiatry at Children's, and Professor of Psychiatry and Behavioral Health at the University of Washington.

Dr. McCauley's interest in the problem of adolescent depression originated in the early 1980s when a 13 year-old boy presented to the emergency room and later to the psychiatry service with all the classic symptoms of adult depression. "At that time," she recalls, "there was still a lot of controversy about whether kids could experience depression." The incident sparked her curiosity and her concern, and in 1982, McCauley and two colleagues embarked on their first inquiry into the causes and course of childhood depression, a seven-year longitudinal study of "Depression in Children and Adolescents" sponsored through the National Institute of Mental Health. "We wanted to know if we could find kids with symptoms of

adult clinical depression and, if so, whether those kids presented with additional problems, what their family history was and what the course of the depression looked like."

From that study and follow-up investigations, McCauley and her colleagues concluded that adolescent depression is very real, and they discovered that risks for depression escalate dramatically during the middle-school years. Children may have depressive episodes before that, but such incidents are usually connected to discrete events or issues. Study data also suggested that while a stable family environment may help children with depression avoid school and social problems

over the long-term, family environment played little role in shaping how depressed children perceived their relationships to their families. Dr. McCauley and her team hypothesized from this that depression in this age group may be related to neurocognitive changes experienced in the adolescent years and to physical as well as hormonal changes associated with puberty.

Interestingly, study results also suggested that girls may face greater risks for depression. This may be due to the fact that girls go through puberty earlier than boys and therefore struggle to manage the intense emotions and complex social demands of early adolescence before they develop the cognitive maturity to effectively deal with these challenges.

Dr. McCauley continued her investigations into the causes and course of adolescent depression over the following decades, focusing on the difficult middle-school years and the transition into high school. Currently, she is involved in three projects dealing with the problem.

The first, the Developmental Pathways Research Program, is a community-based, epidemiological study

Continued on page 12

SPECIAL INTEREST

The Research and Family Liaison

It's early and the room is small. Two children play with toy cars and the third occupies her mother's lap. She dedicates half of her attention to the television and half to her siblings creating a speedway on the floor below. The family has traveled from the suburbs braving morning traffic to hear about what participating in a research study would be like. Mom looks harried already. The presenter begins to explain the purpose of the study and is interrupted as a car collides with her ankle. Would the two older children like to go to the playroom? One lets out a tremendous sneeze and asks his mother for a tissue. "He's been sick for the past week," she explains. Well, maybe they could save the playroom for another day. The presenter turns back to the mother and begins again...

Welcome to consenting in the real world.

As part of the Research and Family Liaison (RFL) role development, **Zuraya Aziz** and **Halle Showalter** have been observing consent conferences to learn about the process at Children's. To further their understanding, Aziz and Showalter have gathered different perspectives on the informed consent process by conducting a family focus group and interviewing researchers. Entering the second phase of role development, they will interview families after observing consent conferences to gather their impressions and suggestions. The RFLs are also planning a focus group with Spanish-speaking families to explore their experiences participating in research.

Regulations are explicit regarding the documentation of informed consent but are vague as to the actual process. A reoccurring theme that Aziz and Showalter

have encountered—both in their experiences with families and in the literature—is that too often the content and language of the consent document becomes the focus. While consent language is very important, more attention needs to be devoted to the presentation of the information during the consent conference and throughout the study. As Showalter explains, "We are discovering that the consent process revolves around creating a relationship between the research team, the participant and the family."

Aziz and Showalter are looking to promote discussion among stakeholders and encourage collaboration around the definition and promotion of good consenting practices. Some challenges in consenting include: concerns about the length and complexity of consent forms; presentation techniques; assessment of understanding; and the impact of language barriers on the consent conference. Opportunities to enhance consent processes incorporate: team consenting, removal of distractions during the consent conference if possible, and techniques to highlight key points during the presentation of research information.

"Ideally," Showalter explains, "we would like to help foster an environment in which researchers and families feel trusted to share their impressions of, questions surrounding, and approaches to the consent process. This will lead to better outcomes for all involved." ~*irm*



Research and Family Liaisons Zuraya Aziz and Halle Showalter

SPECIAL INTEREST

Reconsenting at Age Eighteen

What happens if a child reaches the legal age of consent while enrolled in a study? According to the Office for Human Research Protections (OHRP), the subject's legally effective informed consent must be obtained. If the formerly-minor subject continues to participate in research any prior parental consent or child assent is no longer valid when a subject reaches the age of majority i.e. the age at which a subject's consent is legally effective. Legally effective consent is determined by States – not OHRP – in Washington State the legal age of consent is 18.

Whether a formerly minor subject's consent must be obtained depends on a couple factors: 1) are they continuing to participate in research after they turn 18 (i.e. what research activities are being carried out); and 2) is an Institutional Review Board (IRB) consent waiver applicable. Consent is required from a minor subject that turns 18 while continuing to participate in research if the research activities continue to meet the definition of "human subjects research." Human subject research includes a living individual where data is obtained about them through intervention (physical procedures), interaction (communications or interpersonal contacts) or wherein the researcher obtains private information about the subject. This would include information about behavior that occurs in a context where a person can reasonably expect no observation or recording is taken place.

In a nutshell, a formerly-minor subject's consent must be obtained if they continue to participate in research involving physical interventions – physical exams, blood draws, or other sample collection. This is also true where the continued research activities involve interpersonal contacts or communications with a subject (i.e., data analysis with identifiable subjects) unless the activities are exempt from IRB oversight.

The IRB may waive or alter a formerly-minor subject's consent if: 1) the research involves no more than minimal risk to the subject; 2) any alteration or waiver will not adversely affect the rights and welfare of the subjects; or 3) the research could not practicably be carried out without the alteration or waiver.

For additional information or questions regarding potential impacts to your study please contact the Human Subjects Protection Program at 206-987-7800 or irb@seattlechildrens.org. ~irm

CONFERENCES & TRAINING

2006-07 The Investigator Needs to Know (THINK) Seminar: *Clinical Research - Working with the Media*

When: Tuesday, December 5, 2006

Where: T-639, T-Wing, Health Sciences Building, University of Washington

Time: 4:30 p.m. to 5:30 p.m.

Presenters:

- **Tina Mankowski**, Director, Health Sciences/UW Medicine News and Community Relations
- **Tom Paulson**, Science and Medical Reporter, Seattle Post-Intelligencer Newspaper

The target audience includes principal investigators, along with their administrative staff and trainees, at both UW Medicine and affiliates (Seattle Cancer Care Alliance, Fred Hutchinson Cancer Research Center, VA Puget Sound Health Care System, Harborview Medical Center and Children's Hospital and Regional Medical Center).

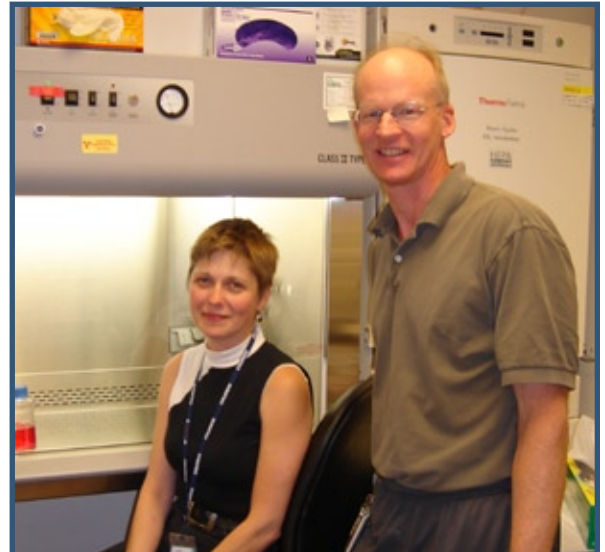
This lecture is open to all faculty, staff and students and will also be simultaneously video televised at affiliated hospitals. Refreshments will be provided. For information regarding the schedule and the THINK Seminar Series please visit the Web site at: <http://www.uwmedicine.org/Research/ClinicalResearch/think.htm>. If you have question about the events please contact Vee White at veewhite@u.washington.edu or (206) 543-8319. ~irm

SPECIAL INTEREST - Global Perspectives on Research at Children's: A 3-Part Series

Part 2: Crossing the Divide - Building Research Resource Bridges to Ukraine

Dr. David Rawlings first met **Dr. Sveta Sidorenko** from Kiev, Ukraine while she was working with Professor Edward Clark at the University of Washington studying B-cell signaling. Based on shared interests, they initiated a collaboration to study the causes of B-cell lymphoma and autoimmune disease. The two did not sever this relationship after Dr. Sidorenko returned to work in her own lab in Ukraine at the R.E. Kavetsky Institute of Experimental Pathology, Oncology and Radiobiology, National Academy of Sciences. When an opportunity to apply for a Fogarty International Research Collaborative Award (FIRCA) presented itself, Dr. Rawlings chose to pursue this R03 grant program to continue this collaboration and to help to carry out experiments that were difficult to perform at the Kiev research facilities.

The FIRCA program facilitates collaborative research between United States biomedical scientists supported by the National Institutes of Health (NIH) and investigators in developing nations, the former Soviet Union and Eastern Europe. The awards are made to a United States institution to support a collaborative research project that will mainly be carried out at the foreign collaborator's research site. In Dr. Rawlings' case, the FIRCA pays for supplies purchased in the United States that are either unavailable or very expensive in Ukraine due to tariff fees and other resource allocation issues. The FIRCA also provides a travel per diem for Ukrainian researchers to come to the United States and carry out research in Children's lab facilities. Overall, the FIRCA creates access to the materials and funds necessary to advance Dr. Sidorenko's lab and the projects of her fellow researchers in Ukraine.



Drs. Sidorenko and Rawlings

Research a World Away

Ukraine is very different from the United States for those in the field of research. Basic laboratory supplies can be hard to find and very difficult to obtain, sometimes taking weeks to arrive. There are very few young investigators because many of these individuals leave for the United States, South Korea or Western Europe to do research at better salaries than they would receive in Ukraine. Many biological materials are scarce or non-existent. For example, the customs process for Ukraine does not have a special route for biological materials; thus, by the time a cell culture or other living lab sample passes through customs, the cells are often dead and useless. This and other obstacles make the expansion and continuation of research in Ukraine a challenging enterprise.

The FIRCA, in line with its mission, has already provided funds for one researcher, **Dr. Svitlana Mikhalap**, to come to Children's to experiment on cell cultures not available in Ukraine. As a result of the collaborative work facilitated by the FIRCA, Dr. Mikhalap was also able to apply for and obtain another independent grant from the U.S. Civilian Research & Development Foundation (CRDF). Next spring, Dr. Sidorenko and a new graduate student will also visit Children's to continue the lab work contemplated under the CRDF and FIRCA awards.

The award of the CRDF grant to Dr. Mikhalap is a direct result of the FIRCA. FIRCA assistance raised the resource level of the Ukrainian lab to the point where it and its researchers could be considered for additional research funding. This result, in and of itself, is a sign of the success of Dr. Rawlings and Dr. Sidorenko's continuing collaboration.

Meanwhile, Dr. Mikhalap is enjoying her time here at Children's, and the feeling is mutual for Dr. Rawlings. In particular, Dr. Mikhalap enjoys the stimulus of working with youthful researchers and sharing ideas with new people. Dr. Rawlings appreciates the contribution of another good scientist in his lab as well as the knowledge that more valuable work is being done here and abroad. ~irm

SPECIAL INTEREST

A New Outcome in Life: Dr. Kristie Bjornson Brings Clinical and Outcomes Research Together for Quality of Life Measurement

Dr. Kristie Bjornson came to Children's 19 years ago to fill-in for a maternity leave and never left. Over the last decades, her role was anything but static: it evolved from Clinical Physical Therapist, to Research Coordinator, and most recently to Clinical Researcher, after Dr. Bjornson completed her doctoral degree. Dr. Bjornson credits her experience working as a co-investigator with Doctors **John McLaughlin**, **Ross Hays**, **Kit Song** and the spasticity management team as motivation to pursue a PhD of her own. The experience she gained working with these clinician/researchers helped form the questions and introduced her to the outcome measures she used in her research, funded by the National Institute of Health, National Institute for Neurological Disorders & Stroke (NIH NINDS).

The focus of Dr. Bjornson's research as well as her clinical work is children with cerebral palsy (CP). CP is a life-long condition that affects a person's neuro-muscular functions. Some individuals are wheel-chair bound, while others are able to walk with few problems. Prior to Dr. Bjornson's recent research, many assumed that the quality of life of a child with CP was determined primarily by his or her ability to walk normally. However, an accurate measure of real-life walking activity did not exist until recently, and self-reported measures of health and quality of life from the children themselves were not taken into account. So Dr. Bjornson asked two questions: How do kids with CP see their health and quality of life, and is it related to their walking ability?

Dr. Bjornson focused her research on a group of children with CP ages 10 to 13 years and a comparison group of youth without CP. A StepWatch™ monitor provided data on the children's walking. Prior to the development of the StepWatch™, the only tools doctors had to measure walking activity were their own eyes, gait labs and pedometers. The StepWatch™ is better than a pedometer because it measures not only number of steps, but intensity and endurance of the subject. This device provides comprehensive real life data and is capable of showing if there is actually improved mobility from therapy and surgical intervention in a child's day-to-day life.

Armed with this new device, Dr. Bjornson also asked the children their opinion regarding their health and quality of life. Surprisingly, the children, no matter what their level of walking skill level, did not perceive their quality of life as any different from other children. They did, however, report that their overall health—including their behavioral and emotional health—was different and that they experienced more pain in day-to-day life.

As a result of her research, Dr. Bjornson now asks every child she works with in her clinic about their pain and their goals in life. Dr. Bjornson aptly notes that what we are doing now with these children has the potential to affect them well into adulthood. Presently, there is little to no information on the results of childhood mobility treatment on adult populations with CP. What we do know is that many adults with CP become less active, and some stop walking altogether. Thus, developing accurate health and quality of life assessment tools is essential to see what works to improve a life as a whole, not just six months into the future. Dr. Bjornson's long term research goal is embedded in this philosophy, and she is currently applying for funding to measure the outcomes of work done now as children grow into adulthood.

Dr. Bjornson's research could reshape how the success of medical intervention is measured and the academic community is listening to what she has to say. Her research is accepted for publication in two journals, *Developmental Medicine & Child Neurology* and *Physical Therapy Journal*, and her abstracts are featured in October 2006 *Pediatric News*. Her goal is to impact practice with better outcomes for children with CP. This result will come with continued work asking questions that rest between the realms of clinical and outcomes research. ~irm



Dr. Kristie Bjornson

CONFERENCES & TRAINING

Free, On-Site Vector NTI Software Training Offered to Researchers

A day-long training session on the use of Vector NTI software was open to all Children's researchers on Sept. 28, 2006, in the Discovery Conference Room at 307 Westlake. Vector NTI is software that enables scientists to design, capture, analyze and format for publication various kinds of life science data. It is free to academic, non-profit and government institutions. A few laboratories at 307 Westlake currently use Vector NTI, and the software could be a useful tool for all bench researchers at Children's. The September training session was not only an opportunity for current users to expand their knowledge of the software, but also a convenient way for research staff to learn about new tools that are available to make their research more efficient and productive.

Vector NTI software can help researchers with:

- sequence analysis, annotation and illustration;
- restriction mapping;
- recombinant molecule design, including Gateway® and TOPO® cloning;
- in silico gel electrophoresis;
- multiple sequence alignment of proteins and DNAs;
- DNA sequence assembly and sequencing project management using the CAP 3 algorithm;
- analysis and annotation of reference genomic DNA sequences; and
- functional annotation of DNAs and proteins.

Of the 32 people that attended the session, one-third was already using Vector NTI and found the training helpful and informative. The rest of the group, without Vector NTI experience, found the software demonstration interesting and useful enough to pursue getting an academic license for their lab. Comments from those that attended were generally positive: "I found that it was quite informative, and it is now easier to use the software for my applications" and "the training was definitely useful, and I believe many will start to use it from now on."

The Research Staff Steering Committee awarded the

funding for this training in an effort to expand training opportunities available to Children's research staff. For more information about how to get a license or user manual for Vector NTI software, please contact **Nina Ellis** at nina.ellis@seattlechildrens.org.~*irn*

SAVE THE DATE!

FELLOWS RESEARCH DAY at Children's Hospital

with keynote speaker

Joseph St. Geme, MD.

Wednesday, April 25, 2007

Joseph St. Geme, MD is Chair of the Department of Pediatrics at Duke University Medical Center. Dr. St. Geme is a nationally recognized expert in basic research and clinical treatment for pediatric infectious diseases. He has been recognized for his research into the genetic and molecular basis of virulence by *Haemophilus influenzae*, and has been involved in efforts to create a pediatric vaccine to prevent these widespread infections, which are often fatal in developing countries. Additional information will be forthcoming. Please hold the date for this day-long event.

Questions? Please contact **Brooke Freed** at brooke.freed@seattlechildrens.org or 206-987-2961.

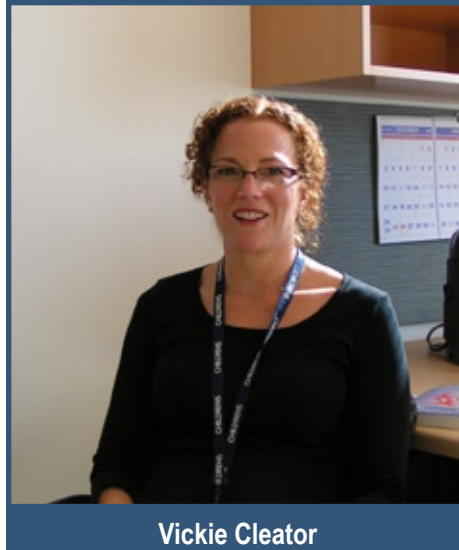
SPECIAL INTEREST

Introducing Victoria Cleator: New Research Institute Facilities Director

Victoria Cleator admits she has the best job in the world. "I get to solve tangible, complicated problems, bring people together and produce a great thing to show for it," she told *interaction* as the sun shone through her office window at the new Seattle Children's Hospital Research Institute.

Vickie is the Director of Research Facilities for the new building at 9th Avenue and Stewart Street, and she is very familiar with the building recently acquired pursuant to Children's Strategic Plan. Vickie's familiarity with the new building began when it housed the previous owner, Corixa. She facilitated the design and construction of the building long before it became the site for the Research Institute. Vickie also comes to Children's with a multitude of experiences from the construction and on-site management of other laboratory facilities.

Vickie came to this work via a slightly indirect route. Born in Toronto, Canada, she and her family moved to Greece when she was nine years old, and she lived there until graduating high school. Vickie then moved to Portland, Oregon, to study biology and enjoy the natural playground offered by the great outdoors of the Northwest. After graduation and working in laboratories as a research assistant and a laboratory manager at Immunex for eight years, Targeted Genetics hired Vickie to manage its laboratory operations. The only catch was that in order to manage their lab, she had to build it first.



Vickie Cleator

This experience, in combination with some on-the-job training followed by the Facilities Management program at the University of Washington, introduced Vickie to the career she loves today.

The key to success for Vickie is decisiveness. "There are a million different details to be decided, and the schedule is always top priority. A lot of other peoples' work depends on decisions being made." The biggest challenge to a new building project is balance—that is, meeting the needs of the stakeholders who will work in the building and meeting the budget. The solution can never be bigger than the problem presented. Experience working in a laboratory is a great benefit, says Vickie. She has an understanding of how people actually operate in a lab setting, and can translate the needs of the individual in the lab to the architect and contractor.

When Vickie is not managing Children's new lab facilities, she

enjoys the plethora of options the Northwest has to offer those who live here. She kayaks, backpacks and hikes in numerous places, but one of her favorite locations is Bend, Oregon. She also recently ran a half-marathon in Vancouver, Canada.

All in all, Vickie is very happy to see the space she worked so hard on be put to use by people who want to use it in its entirety and who love it as much as she does. "When I walked through the lab with **Jim Hendricks**, he was so enthusiastic about the space; I think he liked it more than the former owners." ~*irn*



**We Value
Your
Questions
and
Feedback!**

Have an idea for an article?
Is there a particular topic
you'd like us to cover
in an upcoming issue?
Any questions you'd like
Research Management to
answer for you? We'd love
to hear from you!

**Send your questions,
comments and article
ideas to:**

**[interaction@
seattlechildrens.org](mailto:interaction@seattlechildrens.org)**

PROCESS & PROCEDURE

Fed Ex Kinko's to IKON: Out-Sourced Copy Service Changes for Research Off-Sites

Recently Children's renewed the service contract with IKON which included several important benefits to Children's employees, specifically at off-site locations. Staffing changes with additional on-site management have increased service delivery, both in quantity and quality. Additionally, IKON now offers courier service to off-site locations, including 307 Westlake and Met Park West (MPW).

With these recent upgrades, all research off-site locations are shifting to full time utilization of IKON, away from FedEx Kinko's. All out-sourced copying should be routed as such effective immediately. By utilizing IKON, copy charges will continue to be picked up on a centralized Hospital budget.

How to submit your requests

- Currently requests can be submitted in hard copy form to set drop box locations at research off-sites. For more information contact your off-site representative or the IKON Copy Center.
- Web based ordering is also available! To utilize this method users must first establish an account online by going to the IKON TRAC Solution Web site (<http://seattlechildrens.ikontrac.com/>) and selecting "New User Signup" from the log-in area.

Courier Service

- Daily courier service is available at off-site locations. For more information on schedule please contact your off-site representative.

Have Questions/Need advice on a copy job?

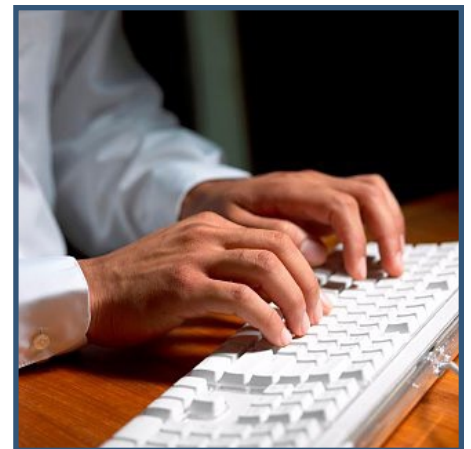
Questions regarding drop box and courier schedule for off-sites can be routed to the appropriate off-site representative or the IKON Copy Center.

- 307 Westlake: **Lisa Cook**
- MPW: **Jena Snook**
- 9S: **Sara Smith**

Questions on navigating the Web site? Need advice on a copy job?

- **Maria Hutchings**, the IKON courier, is available for consultation and questions during her daily trips to the off-site facilities. Request her assistance by filling out a "Consultation Request Slip" located next to the IKON pick up/drop off area with your name, phone number and email address – then drop it into the "PICK UP" box.
- For immediate help dial the IKON Copy Center at (206) 987-4890.
- IKON contact information:
70th/SPW Copy Center, rm S-141
Contact Name: Maria Hutchings
(206) 987-4890; copycenter@seattlechildrens.org

307 Westlake, MPW and the Copy Center Web sites on CHILD are all in the process of updates to reflect this new process. Feedback on the new process should be directed to Jena Snook, jena.snook@seattlechildrens.org. ~irm



PROJECT UPDATES

Study Manager Update

Prior to integrating Study Manager at Children's, the Study Manager Team (SMT) needed to: (1) Establish Billing Compliance and Standard Operating Procedures (SOPs); (2) Understand and standardize current Clinical Research business practices; and (3) Align Study Manager and INVISION reports to facilitate auditing. Over the summer, the SMT made significant progress in three critical areas:

SOP Development and Vetting

In August, the SMT met with the Patient Billing Compliance Advisory Committee (PBCAC) to discuss and review ten newly created SOPs. The SOPs standardize clinical research business practices associated with the implementation of Study Manager. Additionally, the SOPs will provide investigators, research staff and research support services a reference for billing compliance requirements. In addition, a review of the Study Manager project was conducted by Huron Consulting. Huron's findings offered objective confirmation of the direction of the Study Manager project and associated billing compliance processes, as well as offered suggestions for additional business practice clarifications.

Research Patient Care Charging Process Revised

The SMT worked with Business Services, Office of Sponsored Research and Research Finance to assess the current method of directing Research Patient Care Charges. The assessment led to a revision and streamlining of the current process for approving and discounting research billings generated by hospital services. The new process standardized the method for applying the Research Patient Care Rate Agreement (RPCRA) and eliminated the obligation of study staff and investigators to process Blue Sheets. Investigators and Study Staff will continue to receive copies of the Blue Sheet and, if errors are identified, they should contact the Office of Sponsored Research.

Research Billing Compliance Auditing

The SMT finalized a plan to ensure comprehensive auditing of all research patient care charges. Initially the auditing will be completed manually using reports generated from Study Manager and INVISION. The SMT is researching the possibility of developing an automated auditing process between Study Manager and INVISION. ~*im*

SAVE THE DATE: July 13-14, 2007



Current Controversies

Navigating Conflicts When Parents and Providers Disagree About Medical Care

Bell Harbor International Conference Center
Seattle, Washington

PROCESS & PROCEDURE

Change in NIH Grant Deadlines

National Institutes of Health (NIH) announced they have revised the standard grant due dates for submissions to NIH, Agency for Healthcare Research and Quality (AHRQ) and National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC).

The new deadline dates will be effective January 2007 and will apply to both paper and electronic submissions. This change has come about after the transition began from paper to electronic grant submissions. The granting agencies have experienced the challenges of having a very large number of applications be processed on any single day. With the new deadline dates implemented, grants will have multiple submission dates for each round based upon grant type. Spreading receipt of dates for grants will help steady the flow of applications, rather than the typical "boom or bust" cycles which we have worked with for many years. In the link below is a table listing, by grant type, new receipt dates for all three cycles throughout the year. A copy of the deadlines are listed in the table below, sorted by grant type and lists all three cycle deadline dates. The new deadlines will be in effect when RO1's transition from paper to electronic submission effective February of 2007.

Please make sure to visit this announcement as it is CRITICAL to ensure you meet the new deadlines: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-07-001.html>.

Details to note:

1. New deadlines are effective for both paper and electronically submitted grants, effective January 1, 2007.
2. Applications for Requests for Applications (RFA's) and Program Announcements (PA's, PAR's, PAS's) with special receipt dates continue to be due on the specified dates listed in the Funding Opportunity Announcement (FOA).
3. For applications to be considered on time, they must be received by Grants.gov no later than 5:00 p.m. local time for the applicant institution (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-06-050.html>).
4. The proposed dates provide additional time for proposal development for application mechanisms often used by new investigators - R03's, R21's, and K's.
5. The New Investigator R01 date was not changed to avoid affecting the pilot. At present this involves only new investigator R01 applications reviewed in forty study sections in CSR (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-06-060.html>).

Questions? Contact your Children's Sponsored Projects Officer (SPO) if you have additional questions or **Jennie Dodson**, manager, Children's Office of Sponsored Research (206) 987-7822.~*irn*

SPECIAL INTEREST

Elizabeth McCauley: A Research Pioneer in the Field of Adolescent Depression *(Continued from page 2)*

designed to elucidate the causes, contributing factors and the course of development of childhood depression both with and without co-occurring disruptive disorders. The project tracks children between the sixth and ninth grades, and it also involves a screening program to identify students at risk for emotional health problems and link them to services to help them improve their emotional health and achieve academic success.

A second project, the High School Transition Study, is a controlled trial of a school-based preventive intervention program for kids at risk for depression. As McCauley explains, "After you've worked with many youth struggling with acute and significant depression, you naturally begin to think about prevention strategies." The project utilizes a cognitive-behavioral, skills-based curriculum adapted from the Reconnecting Youth program developed by Dr.

Leona Eggert and Ms. Liela Nichlaus from the Department of Psychosocial and Community Health for middle-schoolers. The curriculum aims to teach skills in mood management and communication and to provide students with support in managing the pressures and demands of school.

Dr. McCauley's third project, the Behavioral Activation Therapy for Adolescents, endeavors to develop a manualized Behavioral Activation (BA) Therapy for depressed adolescents and to test its adaptability, acceptability and feasibility. McCauley explains that while researchers have had some limited success with both pharmacological and psychosocial interventions, lingering public concerns about pharmacological interventions and the fact that many teens do not respond to these treatments at all have led to efforts to develop new kinds of

interventions. Behavioral Activation Therapy focuses on helping individuals learn to solve problems, ask for what they want and need from others effectively and to engage in meaningful, pleasurable activities they may have dropped as they became depressed. Recent studies of BA conducted with adults experiencing depression have had promising results, and McCauley hopes that the technique will prove effective and provide a better developmental fit for depressed adolescents.

When discussing her achievements over the last decades, Dr. McCauley stresses the collaborative nature of all her projects. In particular, she mentions core collaborations with her co-investigators, Dr. **Ann Vander Stoep**, child psychiatric epidemiologist of Children's Hospital and the UW School of Public Health and Community Medicine, **Dr. Kelly Schloedt**, psychologist at Children's, and **Dr. Gerald Herting**, UW Psychosocial and Community Health. Additionally, **Drs. Sona Dimidjian**, University of Colorado, **Christopher Martells** and **Kathleen Meyers**, both from UW, have played critical roles in developing the adolescent depression treatment project.

Together, Dr. McCauley and her research partners have succeeded in drawing greater attention to the importance of adolescent depression and mapping out strategies for prevention and treatment. ~*im*



CONFERENCES & TRAINING

Grants.gov Training Opportunity!

Office of Sponsored Research is hosting a NIH sponsored webcast titled "Preparing for NIH Electronic Grant Application", on **Tuesday, December 5th from 10:00 am until 1:00 p.m.** The webcast will be held in the MPW conference room 589.

The presentation will provide an overview of the electronic submission process and use of the SF424 (R&R) and agency-specific forms, walking participants through the submission process. The focus will be on lessons learned and sharing best practices for submitting applications online. To read additional information about this training session, please refer to the announcement, at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-07-009.html>.

Training is open to all investigators, faculty members or staff members who are interested. If you have questions or would like more information, contact **Jennie Dodson** at (206) 987-7822. ~*irn*

Welcome to Research at Children's!

With the continual growth happening within Research at Children's, many new people have found a new home with us. We at *interaction* would like to extend a warm welcome to all who have recently become permanent members of the Research family at Children's!

Joyce Alexander	Office of Research Finance (ORF)	Met Park West	Accountant
Olena Boyarska	Therapeutics Development Network (TDN)	Met Park West	Admin/Program Assistant
Linda Chen	Child Psychiatry Research	Met Park West	Work Study
Trina Colburn	Child Psychiatry Research	Met Park West	Psychometrist
Ashley Deline	Child Psychiatry Research	Child Health Institute (CHI)	Clinical Research Associate
Andrew Gray	Research Support Services (RSS)	307 Westlake	Lead Engineer
Hannah Kerns	Immunology	307 Westlake	Research Technician
Sherry McLaughlin	Infectious Disease (ID)	307 Westlake	Research Scientist
Almut Meyer-Bahlbur	Immunology	307 Westlake	Fellow - MD
Marco Morelli	Therapeutics Development Network (TDN)	Met Park West	Clinical Data Coordinator
Teresa Monaghan	Center for Children with Special Needs (CCSN)	Met Park West	Research Associate
Misty Munns	Emergency Department (ED)	Hospital Campus	Research Coordinator
Kathryn Newton	Surgery	307 Westlake	Research Scientist
Natalie Ottenweller	Research Support Services (RSS)	307 Westlake	Admin/Program Assistant
Dawn Pares	Research Support Services (RSS)	307 Westlake	Admin/Program Assistant
Brian Saelens	Pediatrics	Child Health Institute (CHI)	Principal Investigator
Deborah Skoretz	Endocrinology	Mary Bridge/Multicare	RN
Hilary Stempel	Infectious Disease (ID)	Met Park West	Clinical Research Associate
Keith Tompkins	Infectious Disease (ID)	307 Westlake	Student Helper
Clint Vickers	Office of Clinical Research (OCR)	Met Park West	Research Manager
Teresa Wagner	Cardiology	Met Park West	Clinical Research Associate

RESEARCH BITS

Fifth Annual "Practical Aspects of Conducting Pediatric Trials" Event Goes Off Without a Hitch

A crowd of approximately 60 investigators, clinical researchers and research support staff gathered in Wright Auditorium on Monday, October 16, to take part in the fifth annual "Practical Aspects of Conducting Pediatric Clinical Trials" lecture series, sponsored by the Office of Clinical Research (OCR), the Pediatric Clinical Research Center (PCRC) and the Therapeutics Development Network (TDN) Coordinating Center.

Chief of Research Operations **Erik Lausund** kicked off the day's events by providing a review of last year's highlights and achievements. Lausund singled out for special praise the work of the Research Staff Steering Committee (RSSC) and the process improvement projects undertaken in the last year by the Office of Animal Care, the Office of Sponsored Research, the Human Subjects Protection Program and the Research Specimen Processing Laboratory, and he hinted at great things to come as Children's research enters Phase III of its Strategic Plan.

Following Lausund's remarks, the day's featured speakers took the stage. **Carl Anderson**, senior consultant at Quintiles Consulting, led off with a presentation devoted to "Demystifying the FDA Inspection." Anderson provided an overview of how and why the FDA conducts inspections of clinical research projects, and he offered tips on how to successfully navigate an FDA review.

Next, **Kristy Seidel**, director of the Office of Biostatistical Services, offered her insights on "Data Management and Organization Principles to Enable Efficient Statistical Analysis," providing audience members with a number very useful and practical tips for evaluating statistical software options and for avoiding and ferreting out data entry errors.

TDN Clinical Data Operations Manager **George Strang** followed Seidel with a presentation devoted to "Good Clinical Data Management Practices and Case Report Form (CRF) Development." Strang emphasized the advantages of a well-designed CRF in gathering and managing pertinent and accurate study data, and he carefully described best practices for CRF design and implementation. *~irn*

Our Mission

We believe all children have unique needs and should grow up without illness or injury. With the support of the community and through our spirit of inquiry, we will prevent, treat and eliminate pediatric disease.

Editorial Board



interaction Editorial Office

1100 Olive Way, Suite 500
Seattle, Washington 98101

Phone: (206) 987-1741

E-mail: interaction@seattlechildrens.org

Editor-in-Chief

Heather Lindemann, Department Head, RPM

Managing Editor/Designer

Leslie Holmes, Project Manager, RPM

Editorial Review Board

Teri Balkenende, Program Assistant, MPW

Channing Daniel, Research Manager, OCR

James B. Hendricks, PhD, VP for Research

Leslie Holmes, Project Manager, RPM

Nabeel Khan, Project Manager, RPM

Angel Latterell, Project Manager, RPM

Erik Lausund, Chief, Research Operations

Valerie Madsen, Administrative Assistant, RPM

Jena Snook, Operations Manager, MPW

Brian Williamson, Regulatory Analyst, HSPP

Contributing Writers

Halle Showalter, Research Family Liaison, TKCPB

interaction Photographer

Teri Balkenende, Program Assistant, MPW