



HIGH IMPACT



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Research Ethics and Readability

Left unaddressed, the failure to provide consent forms in easily understood language can compromise the principle of a truly informed consent process. Fortunately, there are simple ways to improve the readability of written consent and assent forms.

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Young Investigator? Start Your Pathway to Independence

The NIH Pathway to Independence Award Program is an innovative, new program that will provide an opportunity for promising postdoctoral scientists to receive both mentored – up to \$90,000 per year – and independent research support – up to \$249,000 per year – from the same award.

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Advertising for Research Participants

In order to assist researchers in the development of advertising materials for recruitment of research participants and to insure that the materials are consistent with Children's Hospital graphic standards, general guidelines have been established for advertising for research participants.

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Non-Competing Award Levels Restored to ~ 97% of Plan

The U.S. Legislature recently passed the Federal Budget for FY2006. The appropriations resulted in a funding reduction of non-emergency, discretionary programs. Read more to find out how this impacts research at Children's Hospital.

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Evolution of Children's IRB Staff Model

Research Meeting Calendar

2/27	Research Management Team Meeting 8:00 a.m.-10:00 a.m.
3/7	"Sneak Peak" of ACB 4:00 p.m.-6:00 p.m.
3/8	Outcomes Steering Committee Meeting 2:00 p.m.-3:00 p.m.
3/9	Staff Steering Committee Meeting 12:00 p.m.-1:00 p.m. 307 Westlake
3/10	Balloon 5 Research Swing Space Moves to ACB
3/10	Clinical Steering Committee Meeting 3:00 p.m.-4:00 p.m.
3/13	Research Management Team Meeting 8:00 a.m.-10:00 a.m.
3/13	Data Sample Size Clinic 4:00 p.m.-5:00 p.m. Hospital G1027
3/16-20	PCRC Closed; Moves to ACB
3/16	Basic Science Committee Meeting 3:00 p.m.-5:00 p.m.
3/20	PCRC Open House in ACB 10:00 a.m.-1:00 p.m.
3/21	Research Oversight Committee Meeting 7:00 a.m.-9:00 a.m.

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High Impact

Research Ethics and Readability

The necessity of obtaining the informed, voluntary consent of research subjects has been recognized as a key principle in ethical research design ever since the publication of the Universal Code of Research Ethics (the Nuremburg Code) in 1947. Yet while health professionals today almost universally recognize the importance of the consent process, many continue to draft consent forms at a level of technical sophistication well beyond most lay audiences. Left unaddressed, the failure to provide study information in easily understood language can lead to delays in gaining ethics approval for research projects. Even more problematic, the practice may also compromise the principle of a truly informed consent process.

The problem is not new. Discussions about how to provide study information that research participants can readily understand are as old as the Nuremburg Code itself. Early debates typically focused on less-educated patients and non-native speakers, who might have greater difficulty understanding written English. These remain important concerns. However, interest in the ability of the broader population to understand health-related materials has grown in recent decades. It is now recognized, for example, that stressors associated with making health decisions can impair a person's ability to comprehend information, and even well-educated individuals may struggle with written materials outside their expertise.

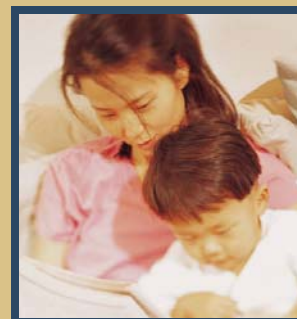
Fortunately, there are assessment tools available to help health care professionals evaluate the readability of their materials. MS Word users are familiar with two examples: the Flesh Reading Ease and the Flesh-Kinkaid Grade Level assessment. Both are accessed via the Word tools menu. Such devices use formulas based on the number of words per sentence and the proportion of single- and multiple-syllable words in a text to generate a readability score. Advantages of these scoring tools are evident: they are quick and easy to use, and they provide tangible measures of reading ease. The tools nonetheless have their limitations. Most, for example, offer no means of measuring the familiarity of the vocabulary used in a text. They do not measure the clarity of writing, and they provide no measure of information density. Quirks in the way that software programs like MS Word "read" text can also make these tools unreliable.

Ultimately, the researcher's best bet is to balance the information provided by readability scoring tools with good judgment. To that end, it may be helpful to keep a few tips in mind when composing materials for families (see right.)

Finally, researchers should remember that the consent form is only the beginning of the consent process. Written material is necessary for patient understanding, but it should never take the place of direct conversations with families. *i*

TIPS for Composing Materials for Families

- Use common everyday words and avoid technical terms.
- Use short, simple sentences.
- Avoid the passive voice.
- Write as though you are speaking to the reader, using "we" and "you."
- Put yourself in the patients' shoes; ask yourself what kinds of questions they might have and minimize information unrelated to what they need to know.
- Ask someone unrelated to the project to read what you have written.



High Impact

Start Your Pathway to Independence

One of the most challenging transitions in any research career is the transition from postdoctoral trainee to independent scientist. The National Institutes of Health (NIH) data indicates that the average age of new principal investigators obtaining R01 research funding for the first time has risen from 37 to 42 years of age since the early 1980s. To address this challenge, NIH Director **Elias A. Zerhouni, MD**, announced the NIH Pathway to Independence Award Program. The program features a new opportunity for promising postdoctoral scientists to receive both mentored and independent research support from the same award.

The initial mentored phase will provide support – up to \$90,000 per year – for research and salary expenses for up to two years. This initial phase of support will allow the candidate time to complete research, publish results, and bridge to an independent research position. As part of the application, the candidate must propose a research project that they will pursue as an independent investigator during the second phase of the award.

Following the mentored phase, the individual may request up to three years of support to transition, as an independent scientist, to an extramural sponsoring institution that has recruited the individual. This support – up to \$249,000 per year – is intended to allow the individual to continue working toward establishing his/her own independent research program and prepare an application for regular grant support.

The goal of this pilot initiative is to facilitate receipt of R01 awards earlier in research careers and to assist investigators in securing stable research positions during the critical transition stage of their careers. The primary, long-term goal of the Pathway to Independence Award is to increase and maintain a strong cohort of new and talented, NIH-supported, independent investigators.

Key Dates

- Application Receipt Date(s): April 7, 2006 and subsequent standard dates, please see <http://grants1.nih.gov/grants/oer.htm> for details.
- Peer Review Date(s): Summer 2006 and subsequent standard dates, please see <http://grants.nih.gov/grants/funding/submissionschedule.htm> for details.
- Council Review Date(s): September 2006 and subsequent standard dates, please see <http://grants.nih.gov/grants/funding/submissionschedule.htm> for details.
- Earliest Anticipated Start Date: October 2006 and subsequent standard dates, please see <http://grants.nih.gov/grants/funding/submissionschedule.htm> for details. **i**

Bye-Bye, Balloon 5 - Research Swing Space Relocates

March will be a busy month for Children's Hospital. With the opening of the new Ambulatory Care Building, many clinics are leaving their temporary facilities, freeing these up to be remodeled. Consequently, the research swing space on Balloon 5 is moving to a new location on the main hospital campus. Please come to either of two information sessions to discuss issues around the *new* Just-In-Time space for Research Staff. The floor plans of the new space will be available for review and staff will be on hand to answer questions about the move. **The move date and time is Friday, March 10, 8 a.m.**

The new space will be ready for use by Monday, March 13.

Funding & Finance

NIH Financial Policy Notice: Non-Competing Award Levels Restored to ~ 97% of Plan

National Institutes of Health (NIH) Financial Policy for Grant Awards – FY 2006 notice (NOT-OD-06-025), dated January 9, 2006, updated the research community on appropriation levels and their impact on non-competing grant awards. Previously operating on a continuing resolution (NOT-OD-06-014), NIH issued non-competing research grant awards at a level below that indicated on the most recent Notice of Award. Generally, up to 80% of the previously committed level was awarded.

The NIH appropriation for FY 2006 included an across-the-board reduction to non-emergency, discretionary programs, which directly impacted NIH's budget. NIH established the following financial policies consistent with this appropriation.

- Research Project Grants (RPG)
 - Non-competing awards will be awarded at a level of 97.65% of the FY2006 amount indicated in the Notice of Grant Award (previous budget year). Future budget periods will be adjusted by the same factor.
 - Non-competing awards previously issued at reduced levels (up to 80%) will be revised to provide a restoration of funds to the 97.65% level. Future budget periods will be adjusted by the same factor.
 - The amounts provided for competing RPGs will be managed to an average award amount equal to FY 2005 levels. FY 2006 policy includes the provision of a 3% escalation factor in the amounts indicated for future years which are not based on modular applications.
- National Research Service Awards (Fellowships and Training Grants)
 - Details are published in a separate notice. (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-06-026.html>)
- Other Grant Programs
 - Other grant programs are managed in accordance with the policies established by each Institute and Center.

Questions regarding adjustments applied on individual grant awards should be directed to the Grants Management Specialist identified on the Notice of Award. **i**

Funding Available for Grant Pre-Review

In the interest of supporting its investigators to successfully obtain extramural funding, Children's Hospital and Regional Medical Center's Basic Science Steering Committee (BSSC) is offering \$200 stipends for grant applications to be reviewed and critiqued prior to formal submission. The purpose behind this offer is to enhance the quality of applications and, more specifically, to improve the likelihood of grant approval.

Funding will come directly from the BSSC annual budget and the application process has been outlined by the committee. Please contact **Craig Rubens**, BSSC Chair, or **Jim Hendricks**, Vice President, Research, with questions about this process. **i**



High Impact

Advertising for Research Participants

In order to assist researchers in the development of advertising materials for recruitment of research participants and to insure that the materials are consistent with Children's Hospital graphic standards, general guidelines have been established for advertising for research participants. These guidelines are outlined below and are posted on the research Web site, in the Institutional Review Board (IRB) section under Information Sheets. Templates for advertisements will soon be available on the site for use by researchers in the development of advertising materials.



Information Sheet – Advertising for Research Participants:

The recruitment of research participants may involve advertisement. Advertising may include brochures, flyers, newspaper ads, public service announcements or postings on Internet Web sites. Advertisements for research participants require the review and approval of the IRB and Children's Marketing Communications (MarComm) Department prior to printing, posting or distributing.

General guidelines for all Children's advertisements for research participants:

The content of an advertisement is tailored to the specific project. Include the following information:

- The participant is being asked to take part in **research**;
- The basic purpose of the research;
- The basic eligibility criteria (e.g., age range, diagnosis);
- A brief description of the project (e.g., whether it involves a blood draw, use of an investigational drug or an interview);
- The time commitment for participants;
- Compensation, payment or inducement participants will receive*;
- How to contact the research team to obtain more information about the research, including name and/or title of contact person (e.g., research coordinator) and ways to contact research team (e.g., telephone number, e-mail address, research study Web site);
- Children's Hospital logo (used per Children's graphic standards);
- The department/division and institutional affiliation of the principal investigator.

*If the amount or type of payment could unduly influence a child or parent's decision to participate, the IRB may decide **not** to describe payment in the recruitment materials.

Submitting the advertisement to MarComm department for review:

- Submit the draft advertisement to MarComm early in the process. Send your request to MarCommRequests@seattlechildrens.org. Allow three business days for review and approval.
- Children's graphic identity standards should be upheld and can be found on CHILD at http://child/about_childrens/marketing_communications_standards/.

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Advertising for Research Participants (Continued from page 5)

- Advertisement templates are available on the Children's research Web site at <http://research.seattlechildrens.org/rss/irb/information-sheets.asp> and should be used for development of advertisements.

Submitting the advertisement to IRB for review:

- Indicate whether or not the advertisement has been reviewed and approved by MarComm.
- Explain to the IRB how and where advertisements will be used and posted.
- When approved, the advertisement will include an IRB approval stamp with approval date.

Inside the hospital:

Flyers, advertisements and brochures may be posted in designated areas (e.g., specific clinics, the Family Resource Center, etc.). Researchers need to work directly with the clinics or Family Resource Center on posting and removing their advertisements. Advertisements may **not** be placed in elevators, hallways or public areas of the hospital.

Outside the hospital:

Researchers need to work directly with the sites on posting and removing their advertisements. **i**



Education & Training

Focus on Fellows

Friday, March 31, 2006 welcomes Children's Hospital's Third Annual Department of Pediatrics Fellows' Research Day. In the interest of bringing focus to the broad scope of both basic and clinical research being conducted by fellows within the department, those chosen to present will do so in either oral or poster format. Oral presentations, which are scheduled to be delivered in Wright Auditorium during the morning, will each consist of approximately ten minutes of lecture time followed by a five minute question and answer session. Posters will be available for viewing in the Anna Clise Board Room on Thursday, March 30 immediately following Grand Rounds. Question and answer sessions concerning the posters will be conducted on Friday afternoon following the oral presentations.

Subsequent to the presentations, 10 winners will be selected to receive awards of \$1,000 each. This year's judges include **Sandra Juul** (Neonatology), **Helen Emery** (Rheumatology), **Margaret Rosenfeld** (Pulmonary) and **Amanda Jones** (Infectious Disease). Joining the committee in the review process is this year's keynote speaker, **Gary L. Freed**, MD, MPH, Percy and Mary Murphy Professor of Pediatrics and Child Health Delivery and the Director of the Division of General Pediatrics at the University of Michigan School of Medicine.

For more information, please contact **Brooke Freed** via e-mail at brooke.freed@seattlechildrens.org or by phone at X72150. **i**

Special Interest

New Approaches to a Devastating Childhood Cancer

Neuroblastoma is a form of solid tumor cancer that occurs in infants and young children. It is rarely found in children older than 10 years. The cells of this cancer usually resemble very primitive developing nerve cells found in an embryo or fetus. The term neuro indicates "nerves," while blastoma refers to a cancer that affects immature or developing cells.

Neuroblastoma is, by far, the most common cancer in infants and the third most common type of cancer in children, with approximately 650 new cases each year. It arises in the peripheral nervous system, and is a unique cancer in that it has distinct groups. Patients can, and do, experience very different outcomes. In as many as 7 of 10 cases, the disease is not diagnosed until it has already spread (metastasized). Despite this, about half of patients will survive the disease with minimal therapy, while the remaining half have approximately a 30% chance of surviving despite aggressive therapy.

This is the disease that drives **Dr. Julie Park's** passion and research. Dr. Park is an associate professor of Pediatrics at Children's Hospital. She is a clinical research physician that has been with the University of Washington (Pediatric Residency Program), Fred Hutchinson Cancer Research Center (Pediatric Hematology/Oncology Program), and Children's Hospital (attending research clinician) since 1991. Her research focuses on developing new therapies for children with the more aggressive form of neuroblastoma. Because of the rarity of neuroblastoma, such research must be accomplished through national collaboration. Dr. Park's work led to the development of a national randomized Phase III protocol within the Children's Oncology Group (COG) for treatment of newly diagnosed

high risk neuroblastoma. In addition, Dr. Park steered our institution in becoming a leading participant in the COG Phase I Consortium and the New Advances of Neuroblastoma Therapy (NANT) consortium, participating in novel therapies for patients with recurrent malignancies including neuroblastoma.

"Neuroblastoma is a fantastic tumor model and is the paradigm in pediatric malignancies for characterizing the molecular basis for tumor behavior," remarks Dr. Park. The ability to apply tumor pathologic and molecular findings to patient prognosis is available now. "The challenge is to take this knowledge and build therapies on it. This is very cool."



Dr. Julie Park

Dr. Park and her colleagues at the Seattle Cancer Care Alliance are taking two approaches toward improving outcome for neuroblastoma: increasing our understanding and ability to maximize current treatments and developing new therapies based upon known tumor molecular pathways. In the former, researchers learn how to build on current therapies, both by introducing novel chemotherapies and by understanding why current therapies either result in poor tumor response or excessive side effects. By analyzing genetic factors known to correlate with how drugs are broken down by the body, known as pharmacogenomics, researchers may be able to predict the outcome of certain treatments – too rapid of breakdown of chemotherapy drugs and less activity against tumor cells, or not rapid enough breakdown causing excessive toxicity. Pharmacogenomics is the branch of pharmaceuticals that deals with the influence of genetic variation on drug response in patients. Dr. Park works closely with **Dr. Jeanine McCune** in this aspect of neuroblastoma research. The latter approach is lab-based and targets the molecular

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Special Interest from the desk of: Pat Hagan, COO

The interplay of research and clinical operations at Children's has always been important. With an even greater focus on our research enterprise and its growth, the effect on hospital operations will be seen in two major ways. First and foremost, it will benefit our patients and employees to be involved with a world-class academic medical center. This is due to the fact that such centers attract the best and the brightest practitioners and are on the cutting edge of treatment options. Second, the increased investment in research will heighten the need to ensure hospital operations are running as efficiently and effectively as possible. This is essential because the hospital is a major source of funding for our research enterprise - in addition to philanthropy, outside foundations, and the government (e.g., NIH funding). Hospital operations currently account for approximately \$13 million per year in research funding. This number will only increase in the coming years.

Continuing to integrate patient care, research, education, and advocacy is key to Children's achieving worldwide prominence. One of the best ways to do this will be through our integrated strategic planning process. The strategic planning work already done over the past 18 months has enabled us to now accelerate our strategic planning initiatives. The strategic plan will more clearly focus the priorities of the hospital, es-

tablish a framework for the needed integration of research and clinical work, and create a common language to discuss our next steps as an institution.

Communication will be a key element in creating an environment of dynamic symbiosis where research and clinical work support each other. One challenge will be to keep the clinical side of the hospital informed about the research being done and to integrate that research into day-to-day clinical operations. Another challenge will be to keep our colleagues in research informed of what is happening with the hospital. Part of this is just a natural function of being busy - it narrows everyone's scope of interest. However, we must strive to keep communication open. We will do this by continuing the communication forums (e.g., Fall Forums) already established as well as creating new opportunities for communication (e.g., solicitations for information regarding issues and suggestions). This will increase the engagement and interplay between the two spheres that will be vital to our success.

The importance of these endeavors is reflected in the Research Division goals for 2006. One goal is to increase NIH grant awards, which is obviously important to supporting research. Such grants also serve as an important measure of how our research is perceived by the greater research community. Another goal is to contain research infrastructure costs because we



want the same efficiency and effectiveness in research as we seek in the hospital overall. The research goal of completing Continuous Performance Improvement (CPI) workshops and publishing related manuscripts is dual in nature. We use CPI principles because they employ scientific methodology and engage all of us to improve processes and procedures. But another aim of the CPI work in the Research Division will be to attain academic credibility for the work itself. We hope that this method of improvement will ultimately provide benefits for the larger medical community. This will depend upon our success in implementing the method in a way that attracts outcomes academics to study our improvement efforts and publish the findings in peer reviewed journals.

Children's is in the process of making the transition to a more fully multi-faceted institution - with research playing a larger part than ever before. Together, with the leadership of our Chief Executive Officer, **Dr. Tom Hansen**, and the Board of Trustees, we will meet the challenges of becoming a world class institution and the best children's hospital in the country. *i*

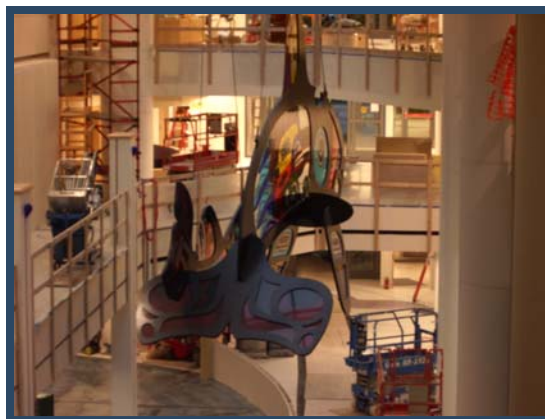
High Impact

PCRC Moves Into Its New Home

The Pediatric Clinical Research Center (PCRC) will be closed on Thursday and Friday, March 16 and 17, and on the morning of Monday, March 20, to allow for the center's transition into the new Ambulatory Care Building (ACB). The new building has been almost six years in the making: pre-design planning began back in the summer of 2000 and actual construction in 2002. Now, over 30 on-campus specialty clinics stand poised to relocate to the new facility over the course of the next several months.

The PCRC staff has good reason to be excited about the big move. Located on the 6th floor of the ACB, near the Hematology-Oncology clinic, the new, larger site will provide over 2000 square feet of added research space, with four additional exam rooms, a bigger lab, a sleep study suite and a dedicated blood draw room. The new space features a cozy waiting and reception area (room W-6605), which will provide access to the new space. Children's employees and families will also appreciate the central location of the new PCRC unit on the hospital campus, near diagnostic services, parking and registration.

"The new ACB furthers Children's mission to be the best pediatric hospital by providing our families with convenient, centralized access to all of Children's on-campus specialty units," explains Vice President for Research, **Jim Hendricks**. "In providing a state-of-the-art PCRC facility to house Children's multi-disciplinary research endeavors and diagnostic ser-



Whale sculpture graces the new lobby.



ACB under construction.

VICES, the building also supports Children's research expansion ambitions."

Ambulatory Services have scheduled a series of events for those interested in seeing the new building and learning more about its operations. For starters, Children's employees, volunteers, providers and families are all invited to attend a special "Sneak Peak" of the new facility on Tuesday, March 7, between 4 and 6 p.m. For those who cannot wait until March, Ambulatory Services is also hosting a series of tours of the building on Wednesday and Thursday afternoons during the month of February. Space is limited and tours are filling up fast, so interested parties should contact **Jerrie Bishop** (x74572) soon for sign-up details. Children's employees can also find full details regarding the new facility and the move—everything from move calendars, to process improvement work plans and pictures of the new building—on

the Ambulatory Services home page on CHILD. (http://child/departments/ambulatory_services/home/home_page.asp).

The PCRC is also planning an open house in its new space for the morning of Monday, March 20, between 10 a.m. and 1 p.m. Those attending will enjoy staff-led tours of the new unit as well as refreshments. The center will get down to the business of seeing subjects again that afternoon. Those with questions or comments about the PCRC move are asked to contact **Pam Joy** (x73348) or **Sharon Schneider** (x71793). *i*

Evolution of Children's IRB Staff Model

from the desk of: James B. Hendricks, PhD, Vice President for Research

Late last week, the Institutional Review Board (IRB) staff was informed that I had approved changes in the education requirements of their work content descriptions that effectively disqualified them for continued employment. This difficult decision was driven by best practice studies that suggested we could achieve improvements in Children's IRB turn-around-time by employing a different staffing model. This decision was not made hastily; rather, it was guided by benchmarking studies and statistical analysis over a two year period. I have summarized what we learned below.

What We Learned

The average turn-around-time (TAT) for full IRB review between 2003 and 2005 is shown in Table 1. Average TAT increased over this period and today measures approximately four months (with a range of three weeks to nine months). Is this too long? It is difficult to benchmark IRB TAT because there is no standard measurement interval. Our TAT is measured from the date a protocol is received in the IRB Office to the date the IRB Chair signs the approval letter. Based on an analysis of best practices, we have concluded that 20 working days (approximately one month) is an achievable goal. Striving for best practice is consistent with our vision and essential if we are to achieve research excellence.

Table 1. Turn-Around-Time for Full IRB Review, 2003-2005

Year	Average TAT (\pm SD)*
2003	58.6 \pm 42
2004	69.9 \pm 49.5
2005	85.7 \pm 46.5

* working days

In early 2004, I instituted a "checkpoint monitoring system" to measure flow through the various stages of the full review process. This system was designed to break down total TAT into six process-oriented intervals: (A) application receipt date to date pre-review completed, (B) date pre-review completed to date of IRB meeting, (C) date of IRB meeting to date PI notified of contingencies, (D) date PI notified of contingencies to date response received by IRB, (E) date of receipt of response from PI to date contingencies removed, and (F) date contingencies removed to date IRB Chair signs approval letter. The purpose of this analysis was to better understand which parts of the IRB review process contributed most to total TAT. Figure 1 shows checkpoint statistics for 2004 and 2005. It is clear that pre-review time (checkpoint A) and PI response time to contingencies (checkpoint D) contribute most to TAT.

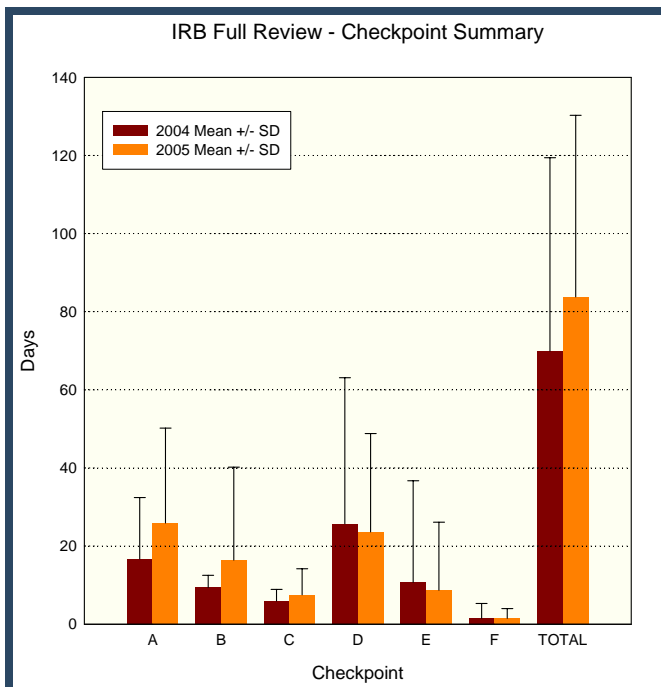


Figure 1. Checkpoint statistics for IRB TAT in 2004 and 2005.

To examine the relationship between TAT and staffing levels, we consulted several institutions considered to employ best practices. For instance, the University of Wisconsin Health Science Center (UWHSC) IRB, with an average TAT of approximately one month, is staffed with one analyst per 100 new protocols. Children's IRB processes approximately 125 new protocols per year and is staffed by three analysts (exclusive of the manager and administrative support person). UWHSC Professor **Norm Fost** attributes his institution's short TAT

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to its requirement that IRB analysts have an advanced degree. Dr. Fost, a highly regarded pediatric bioethicist, explains that the advanced degree helps analysts quickly assess research design and its relationship to risk and expected or anticipated benefits in the pre-review stage. The interaction between these highly trained staff and investigators leads to fewer contingencies, faster turn-around-times, and less work for the IRB committee.

Translating What We Learned into Practice

Based on our work over the last two years, we learned that: (1) despite the hard work of current IRB staff, our full review TAT exceeds best practice benchmarks, (2) current IRB staffing levels exceed best practice benchmarks, (3) staff pre-review and PI response to contingencies are the most important contributors to our TAT, and (4) the use of analysts with an advanced degree (e.g., PhD, JD) may reduce TAT by reducing contingencies. As I see it, we have two options: (1) maintain the status quo and accept a four month average TAT for full IRB review or (2) institute best practices and change our IRB Office staffing model. Given our vision to be the best children's hospital, I considered option 1 to be out of the question and ordered implementation of the IRB staffing model shown in Figure 2. This model incorporates best practices from academic and commercial IRBs. Each Children's Hospital IRB (designated IRB A and IRB B) will be assigned a project manager (with appropriate national certification) responsible for managing the flow of applications through that IRB. The project manager will be responsible for managing communications and the flow of paperwork between investigators, IRB analysts, and the IRB. IRB analysts will work in teams consisting of a scientific analyst with a PhD in the biological sciences and a regulatory analyst with a JD concentration in health policy. Based on our existing volume of new applications, initially one PhD/JD team will be hired. Oversight responsibility for IRB staff will be the charge of the new Director, Office of Institutional Assurances. The Search Committee for this position has initiated interviews with the top three candidates, and it is my hope that this position will be filled by June 1, 2006.

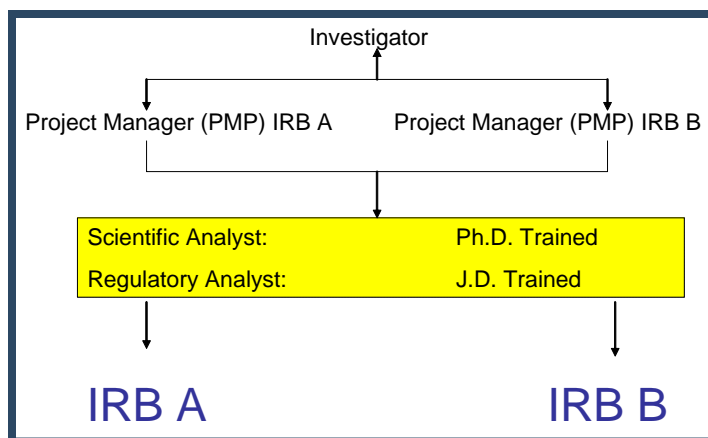


Figure 2. New IRB Office staffing model.

What is the Interim Plan?

Existing IRB staff will be employed through March 31, 2006. A team of contract employees with scientific and regulatory experience is already working alongside existing staff, and will maintain the status quo until our new model can be fully implemented. I will be actively involved in application pre-review until a scientific analyst is hired. I have substantial experience in this area, having served both as an investigator and IRB member. Recently, we joined in discussions with the University of Washington and Fred Hutchinson Cancer Research Center aimed at creating a single IRB application for use by all three institutions. We are also working toward executing a reciprocity agreement that would recognize IRB approval by these institutions.

Concluding Remarks

I know that these changes have taken many of you by surprise, and that you are concerned for the welfare of active and planned studies. Although medical leadership was apprised of these changes well in advance, a general announcement could not be made until IRB staff and the IRB had been duly notified. I have also notified the Office of Human Research Protection (OHRP) of these changes, and have invited them to inspect our program at any time. I can assure you that current and planned studies will not be impacted by these changes, nor will our responsibility to protect and ensure the welfare of research participants. **i**

New Approaches to a Devastating Childhood Cancer (Continued from page 7)

pathways that seem to be important in promoting tumor growth or tumor resistance to current standard therapies.

Laboratory work accomplished by **Drs. Jim Olson** and **Sue Spiller** (faculty in the division of Pediatric Hematology/Oncology) has revealed that a family of agents, histone deacetylase inhibitors, can enhance the ability of retinoids (a standard class of drugs used to treat neuroblastoma) to cause tumor cell death. This pre-clinical work has been integral in the development of a COG Phase I protocol that will evaluate the combination of a histone deacetylase inhibitor with retinoic acid in pediatric patients with recurrent malignancies.

Neuroblastoma is, by far, the most common cancer in infants and the third most common type of cancer in children, with approximately 650 new cases each year.

“The success of our clinical research is truly a team effort. From SCCA collaborators and faculty colleagues equally committed to improving outcome for childhood malignancies to our incredibly talented and dedicated Phase I research team (**Serina Gisburne, Celeste Oglesby, Sara Muchinsky,**

and the Pediatric Clinical Research Center). It would not be possible for one institution to efficiently run multiple trials of new agents,” notes Dr. Park. “Being a leader in consortium groups allows us to bring new ideas to the forefront and to help get the research accomplished. This must be performed efficiently if we are to someday improve the outcome for newly diagnosed patients.” **i**

Process & Procedure: Promote Your Research

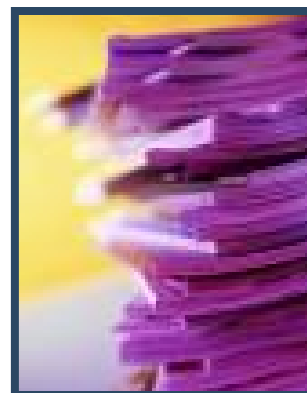
The Marketing Communications (MarComm) Department wants to promote research at Children's. They are requesting updates from investigators on completed research (after papers have been accepted but before publishing), and research grants and awards. The objective is to increase awareness of research and investigators at Children's and to give researchers the recognition they deserve.

Researchers can fill out the Research Notification form (<http://research.seattlechildrens.org/about/tell-us-your-research.asp>) on the Forms and Policies page of Children's Research Web site.

The information you submit may be used to help advance our vision to be the best children's hospital and our mission to prevent, treat and eliminate pediatric disease. Among the various communications vehicles that will receive information submitted with the Research Notification form are *interaction*, Connection magazine, InHouse, Foundation and Guild newsletter, Children's research Web site and press releases. The form will ask for accomplishments in the following areas:

- Research paper/journal article
- Grant award
- National leadership positions
- Personal or group award
- Clinical advancement or procedure
- Staff story

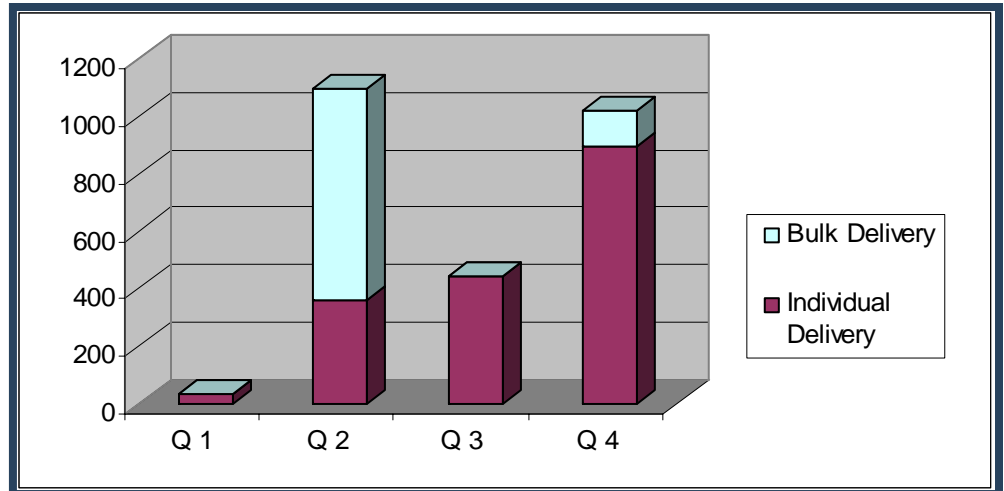
If you have questions about the form or the process, please contact **Jennifer Seymour** at Jennifer.Seymour@seattlechildrens.org or x75207. **i**



Stats

**OCR Specimen Processing Laboratory (OCR-SPL)
Oh, What a Year!**

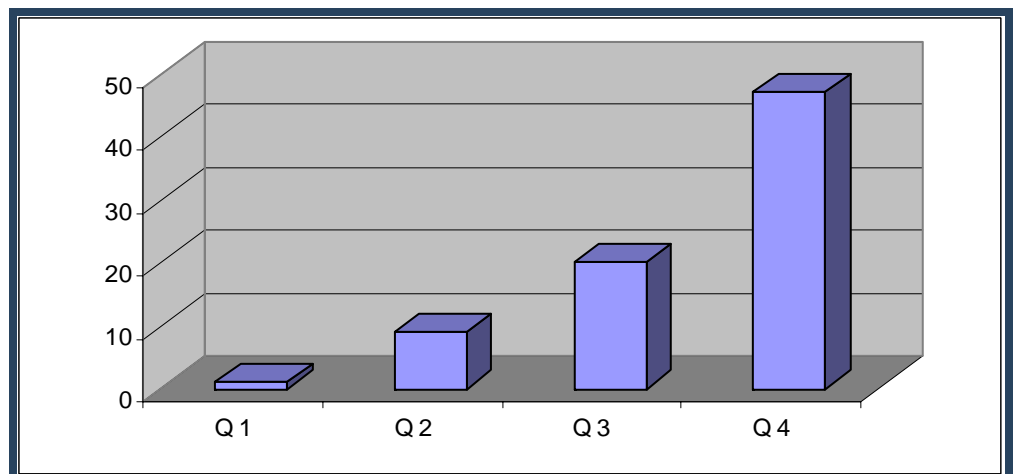
Since its inception in November 2004, the Office of Clinical Research Specimen Processing Laboratory (OCR-SPL) has provided resources to clinical research investigators and staff for the handling, processing, storage and shipping of research specimens. Figure 1 shows in the first quarter of 2005, the lab assisted with the processing, shipping and/or coordinating of 33 samples. By the end of 2005, that number had increased to 2,596 samples!



Bulk Delivery	0	739	0	126	865
Individual Delivery	33	358	444	896	1731
FY 2005 Totals	Q 1	Q 2	Q 3	Q 4	2596

Figure 1. FY 2005 Total Number of Specimens to OCR-SPL

At the end of 2005, the lab was supporting 47 clinical research studies (see Figure 2 for Active Studies) from nine different divisions. As of February, 2006, those numbers have increased to over 60 studies from 11 different divisions. Currently, the Infectious Disease Division is the largest customer, with 48% of the specimen volume. Hematology Oncology is the second largest division utilizing the lab, with 27% of the samples (see Figure 3 on page 14.)



Active Studies	1	9	20	47
FY 2005 Totals	Q 1	Q 2	Q 3	Q 4

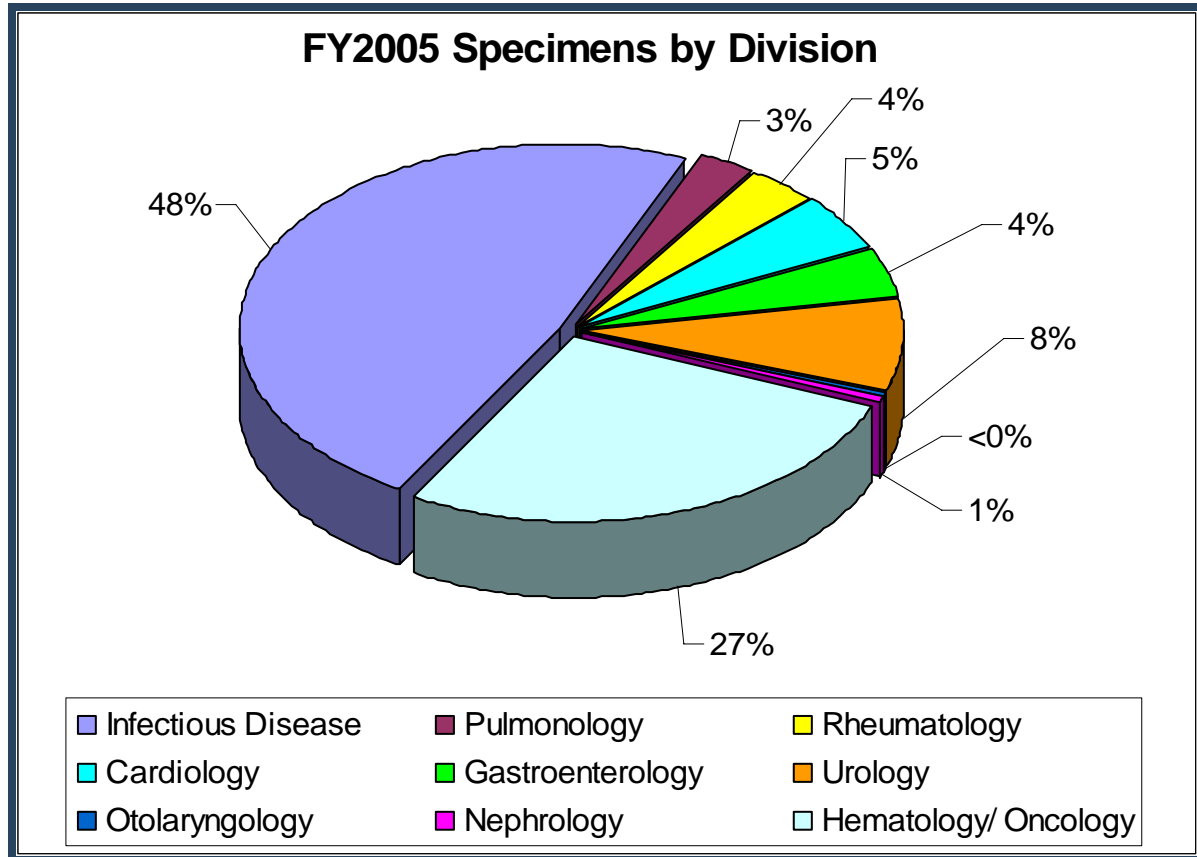
Figure 2. FY 2005 Total Numbers of OCR-SPL Studies

In order to continue to meet the specimen handling, processing and storage needs of clinical researchers and staff, the OCR-SPL plans to expand the volume and type of services it provides over the coming year. Stay tuned for updates in upcoming issues of *interaction*.

For more information about accessing OCR-SPL services, please contact **Pam Joy** at x77863 or **Christine Phillips** at x71875. *i*

Stats

OCR Specimen Processing Laboratory (Continued from page 13)



	Total	Infectious Disease	Pulmonology	Rheumatology	Cardiology
FY05 Total Specimens	2596	1244	77	92	130
by percentage	100%	48%	3%	4%	5%

	Gastroenterology	Urology	Otolaryngology	Nephrology	Hematology/ Oncology
FY05 Total Specimens	112	214	6	13	708
by percentage	4%	8%	0%	1%	27%

Special Interest

Downtown Is the Place To Be! Child Psychiatry Research Moves Downtown, Coincides with Opening of MPW Research Clinic

Child Psychiatry Research said goodbye to their space on Lake City Way for the downtown location of Metropolitan Park West (MPW) in early February. After several months of planning, the move finally occurred. Computers and moving crates from the Lake City Way location, Child Health Institute (CHI) and the hospital arrived in time for Child Psychiatry Research to unpack and get back to business as usual on Monday, February 5. Roughly 35 people strong, this group now occupies the southwest corner of Children's MPW 8th floor.

Coinciding with this latest move, the MPW Research Clinic opened its doors Monday, February 13. Currently seeing research participants enrolled in **Dr. Matthew L. Speltz's** "Neurobehavioral Correlates of Craniosynostosis" study, the clinic boasts four beautiful observation rooms, three with state-of-the-art digital recording equipment, and a waiting area for families, all separate from the Children's employee space at MPW. The "Neurobehavioral Correlates of Craniosynostosis" study (also referred to internally at Children's as the "Infant Learning Project") is funded by the National Institute of Dental and Craniofacial Research. In the near future, the MPW Research Clinic will also likely support research participant visits for two additional studies, **Dr. Matthew L. Speltz's** "Neurodevelopment Among Infants with Deformational Plagiocephaly" and **Dr. Heather Carmichael Olson's** study, "Intervention for Individuals with Fetal Alcohol Syndrome: Transitioning Science to Community Project."

For more information about the MPW Research Clinic, contact **Jena Snook**, MPW operations manager, or **Erik Lausund**, chief, research operations. *i*



Views from the MPW building downtown.



One of the observation rooms with state-of-the-art digital recording equipment.

Project Update: ERP

ERP has been live for just over 11 months now. While a few of us may be wondering how we ever lived without it, most of us are still struggling to answer "How do we live with it?" Research Support Services is working with the Hospital ERP Project Team on a number of key issues with the system. The top two concerns are the time it takes to run a report and the frequency with which reports fail to run. In working through this process, we have collected baseline data on how long it takes to perform certain tasks within the ERP reports system. The two points below may help principal investigators (PIs) with the current on-line reporting set-up, as well as setting expectations:



1. Once the initial report selection screen loads and the parameters surrounding the report you wish to run (e.g., report type, date range, PI number) have been selected, the reporting system is currently experiencing mean report load times of between 30 and 90 seconds. This time fluctuates depending on the amount of activity in a PI's grant portfolio. If a report fails to load (which on certain days can occur), exit the ERP system, and then log back in and attempt to run the report a second time, entering the PIN and PI number carefully. The ERP system may attempt to run a report even if the user input information is incorrect, and thus may produce a blank report or fail to run a report under these circumstances. If a report still fails to load, we suggest waiting until later in the day or the next day to try again, as there may be a system problem behind the scenes (e.g., the server may be down). Our data has shown that reports are four times as likely to fail to run if the attempt is made in the morning, as compared to the late afternoon.
2. Paging through the online reports is currently painfully slow. Our baseline testing revealed that it took an average of 22 seconds for the on-line report system to move from one page to another. It is much quicker to export the reports to an Acrobat PDF format. Expect that it will take 30 seconds for a portfolio to convert to a PDF (although large portfolios may take around 2+ minutes). The advantage for a longer multi-page report is after the initial conversion to a PDF, the reports can be paged through as fast as one can click. Alternatively, the PDF can be printed to a hard copy for later review. The ERP system has the functionality to perform this conversion to a PDF. The user should simply click on the grey export button (second from the top left), select PDF from the drop down menu, and select 'ALL' pages.

Once within the ERP reporting system, are you reviewing your reports on a regular basis? To assist compliance with the Office of the Vice President for Research (OVPR) Policy #6 'Fiscal Responsibilities of Principal Investigators', the PI and budget manager should be reviewing these key financial reports on a regular basis throughout the year. Although the reports are updated daily, a monthly review is considered reasonable. As a reminder, there are a number of essential reports available to understand the activity on your project. The list below is an overview of three of the basic reports:

1. The 'GM Award Summary for a PI' provides a one page snap shot overview of the current revenues and expenses charged to your grant/contract. From a review of this report, you may wish to gather more information on your grant by running one or more of the following reports:
2. 'GM Grant Expenditure Report for a PI'. Simply select a date range of interest and a report detailing the individual expenditures to your grant can be reviewed.
3. 'GM Labor Report, Current for a PI' provides the names and hours charged by Children's staff working on your project(s).

Research Support Services is committed to working with ERP management to make sure that these report times improve in the short-term future. We will update you on our progress through the course of the next six months. *i*

Research Committees: Staff Steering Committee

The newly formed Research Staff Steering Committee (RSSC) would like to recognize the following individuals who have been elected to represent their respective research groups on the RSSC:

- [Kaitlin Jaccard](#)- 307 Westlake Research Support
- [Mary Hackett](#)- 307 Westlake Bench Research
- [Nina Ellis](#)- 307 Westlake Bench Research
- [Ben Harmeling](#)- 307 Westlake Bench Research
- [Toni Lindquist](#)- MPW Research Support
- [Jo Bloch](#)- MPW Research Support
- [Amy Anderson](#)- MPW 8 Research
- [Kelly Worrell](#)- MPW 8 Research (Nursing)
- [Gail Hovick](#)- TDN
- [Chris Clarke](#)- 8P/G
- [Nicole Jacobs](#)- 8P/G
- [Serina Gisburne](#)- (Chair), MPW 8 Research

While the meetings are open to all, staff members are encouraged to contact their representatives with any issues. E-mail links have been provided (click on member names above) for research staff to contact their respective representatives and bring suggestions, concerns, announcements, etc. to their attention for communication to the RSSC.

The RSSC meets the second Thursday of every month from noon to 1:00 p.m., rotating between Met Park West (MPW), 307 Westlake and the main hospital campus. *i*

MEETING DATES 2006	TIME	LOCATION
Thursday, March 9	12:00-1:00 p.m.	307 WL (323)
Thursday, April 13	12:00-1:00 p.m.	Hospital (SDR2)
Thursday, May 11	12:00-1:00 p.m.	MPW (845)
Thursday, June 8	12:00-1:00 p.m.	307 WL (323)
Thursday, July 13	12:00-1:00 p.m.	Hospital (SDR2)
Thursday, August 10	12:00-1:00 p.m.	MPW (589/591)
Thursday, September 14	12:00-1:00 p.m.	307 WL (323)
Thursday, October 12	12:00-1:00 p.m.	Hospital (SDR2)
Thursday, November 9	12:00-1:00 p.m.	MPW (845)
Thursday, December 14	12:00-1:00 p.m.	307 WL (323)

Project Update

Confirming Scope: Study Manager Update

Scope: The Study Manager Project Team is meeting this month to finalize the scope of this project, a key component of success with any project. Incorporating input from research staff and faculty, the team will use project management techniques to develop a work breakdown structure (WBS) that groups project elements to organize and define the total span of the project.

Planning: The next steps include validating the WBS, and using it as a tool to update key project planning documents such as the schedule, project charter, and team roles and responsibilities matrix. While this planning phase takes time, this due diligence will facilitate a successful deployment. Projects most often fail when this step is rushed. The planning team is taking the necessary steps to ensure smooth implementation of *Study Manager* with the least amount of problems.

Communication: The Patient Billing Compliance Advisory Committee, whose role is to guide the project team, will be briefed as the planning documents are completed. Project demonstrations have been taking place since last December and have provided a forum for faculty and staff to view an actual version of the software, ask questions and voice concerns. These demonstrations will continue as part of the ongoing activities to raise awareness about the functionality of *Study Manager*.

History: Children's acquired *Study Manager*, which is a commercial clinical trial management system from Advanced Clinical Software that will assist in adherence to the University of Washington policy of Billing Compliance in Clinical Research. *Study Manager* is a proven product used by over 1,700 hospitals and academic medical centers.

Questions? Contact **Birute Curran**, Office of Clinical Research, or **Scott Larson**, Office of Research Project Management. *i*

Research Bits

Scott Larson Joins Research Project Management

Scott Larson joins Research Project Management (RPM) after completing a career in the U.S. Coast Guard where he served in a variety of assignments throughout the country and specialized in information technology management. In his last assignment, he was a project implementation manager for Rescue 21, which is a major project to modernize the Coast Guard's nationwide, coastal search and rescue system.

Scott is certified as a Project Management Professional (PMP) by the Project Management Institute. In addition, he holds a Bachelor of Science degree in Telecommunications Management from Golden Gate University in San Francisco, California and a Master of Arts degree in Telecommunications from George Mason University in Fairfax, Virginia.



Scott Larson, PMP

Scott will be the project manager for the Billing Compliance in Clinical Research policy initiative, which includes *Study Manager*. His project management experience complements the clinical trial expertise already present in the Office of Clinical Research (OCR) and Office of Sponsored Research (OSR). These offices, together with RPM, will collaborate to ensure that Children's adheres to the billing compliance policy. **i**

Research Bits

Welcome Jennie Dodson, OSR Manager

January 17 saw the end of a long search for the Manager of Sponsored Research. **Jennie Dodson** comes to us with more than 16 years of research management experience, most recently as a division administrator for the University of Washington Department of Medical Oncology at the Seattle Cancer Care Alliance. Previously, she was also employed at Fred Hutchinson Cancer Research Center. Raised in Bellevue, Washington, Jennie obtained her Bachelor of Arts degree from the University of Washington.

Jennie sees her role in the Office of Sponsored Research (OSR) as leveraging her extensive knowledge base, skills and experience to bring programs together collaboratively. She will first address issues within the OSR.



Jennie Dodson

"I am focusing efforts on defining and streamlining OSR processes, with communication going out to faculty, senior leadership and research staff shortly. I will also be working with research programs and OSR staff to ensure that all aspects of research grants, contracts and associated agreements are streamlined and compliant."

Jennie is located with the OSR team in the Metropolitan Park West building and is excited to join the Children's organization. **i**

Research Bits

Office of Sponsored Research Preparing for Grants.gov Submissions

On January 11, the Office of Sponsored Research (OSR) attended Web cast training on the National Institutes of Health's (NIH's) new electronic grant application process and the SF424 Research and Related (R&R) forms. This initial training, with a goal of providing comprehensive understanding of the electronic submission process and the new SF424 (R&R) application, served as the first step in the transition to electronic submission. Topics covered included:

- Registering and submitting an electronic application via Grants.gov;
- Registering and completing the application process in the eRA Commons;
- Step-by-step walk through of the SF424 (R&R) application, assembly and submission.

Now that the introductory course has been completed, the OSR is discussing their internal roll-out, information dissemination and training plan. Look to future *interaction* issues for updates.

It is important to note that all researchers who plan to apply for federal funding during their career are required to have an eRA Commons userID. As this step can take several days, it is suggested that researchers apply for an eRA Commons userID in the near future, rather than waiting until the application is made. Please contact your Sponsored Projects Officer for information about how to accomplish this. **i**

Research Bits

Families on MPW Shuttle?

That is right! Research participant families are now allowed to ride the MPW Shuttle to and from the hospital and MPW for their appointments at the MPW Research Clinic. Riders of the MPW Shuttle may begin to see families aboard as early as February 21, 2006. Families with small children will be responsible for providing their own child safety seat. With this added ridership population, it is a good time to remember to be careful what is discussed on the shuttle. Make sure it is appropriate for public consumption! Direct questions/concerns to **Jena Snook**, MPW operations manager, or **Jim Sawyer**, security services director. **i**

Editorial Board



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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.

Children's
Hospital & Regional Medical Center