

interaction

Research News

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PI Matters Issues of Interest to Investigators

INDIRECT COST RATES TO CHANGE

Children's recently renegotiated its federal indirect cost rate (facilities & administrative cost rate) with DHHS. The following rates will be effective October 1, 2005 for all grants and contracts:

- Bench rate at Children's main campus—72%
- Bench rate at Westlake facility—82%
- Clinical/outcomes rate on-site—41%
- Clinical/outcomes rate off-site—34%

See "Q&A on IDC" about indirect costs (page 3) for more information.

ERP BLUES

As you know, Children's Hospital recently deployed an Enterprise Resource Planning (ERP) system capable of integrating business processes and data from Human Resources, Payroll, Finance, Grants Management, and Purchasing. The ERP system has replaced the legacy systems CODA, Genesys and Matkon, among others. While the system selected by Children's ERP Guidance Team has a good track record of performance at hospitals across the nation, its "grant module" is a beta version not previously implemented. Staff in our Sponsored Research and Finance Department are working hard to overcome problems and issues associated with this system. To address faculty/staff concerns, and ensure that the final design of the grant module meets faculty/staff expectations, an ERP-Research Task Force has been created. The Task Force, Jim Bassuk, Jim Hendricks, Amanda Jones, Erik Lausund, James Parr, David Rawlings, Bruder Stapleton, Kelly Wallace, and Danielle Zerr, recently met to review major issues, and plans to meet monthly to address progress. Meeting dates will be published so that interested faculty/staff can attend and express their opinions.

NEW FEDERAL RESEARCH MISCONDUCT POLICY TIGHTENS DEFINITIONS, ADDS DETAIL

Changes in policies and procedures for handling allegations of research misconduct became effective with a new regulation (42 CFR Part 93) on June 16, 2005. The new regulation, which can be found at the Office of Research Integrity (ORI) web site (<http://ori.dhhs.gov>), introduced the following changes:

- **Applicability.** The new rule includes PHS intramural research programs and contracts that support research, research training, or activities that are related to research or research training. The new rule applies to an allegation that PHS-supported research involving peer review has been plagiarized.
- **Limitations Period.** The new rule is limited to research misconduct occurring within six years of the date on which the institution (or HHS) receives an allegation of misconduct.
- **Definition of Research Misconduct.** The new rule uses the term "research misconduct" rather than "misconduct" or "misconduct in science" and, among other changes, defines this term to include misconduct occurring in connection with the "reviewing" of research.
- **Burden of Proof.** Consistent with the Office of Science and Technology Practice guidance that the exclusion of honest error or difference of opinion from the definition of research misconduct does not require HHS and the institution to disprove possible honest error or difference of opinion

RESEARCH MEETING CALENDAR

9/13	Jivin' with Jim Westlake Faculty 11:30am-12:30pm
9/14	Employee Picnic 11:30am-1:00pm At Both MPW & 307 Westlake
9/16 & 9/17	South Lake Union Block Party at Westlake & Denny
9/20	Jivin' with Jim MPW Staff 11:30am-12:30pm
9/20	Research Oversight Committee 7:00am-9:00am
9/22	Research Executive Committee 4:00pm—5:00pm
9/27	Jivin' with Jim MPW Faculty 11:30am-1:00pm
9/29	MPW Open House 9:30am-12:30pm

PI Matters continued from page 1

ion, the new rule provides that these elements are an affirmative defense that the respondent has the burden of proving by a preponderance of the evidence.

- Institutional Responsibilities. The new rule describes in greater detail the responsibilities of the institution in responding to allegations of research misconduct. Institutions must take steps to ensure a fair and thorough investigation, such as securing the evidence and giving the respondent opportunities to access the evidence and comment on the investigational report.
- Hearing Process. The new rule sets forth a detailed hearing process that is modeled on the HHS Office of the Inspector General regulations. Among the changes is that the trier of fact will be an Administrative Law Judge rather than a three-person panel of the Departmental Appeals Board.
- Children's Hospital's policy on "Handling and Reporting Possible Research Misconduct" (OVPR Policy 1) has been modified in accordance with the new regulations and will be viewable from the research web site. (See page 6.)

HIPAA AUTHORIZATIONS REQUIRED FOR RESEARCH

Recent research compliance evaluations of ongoing research reveals a consistent pattern of investigators failing to obtain HIPAA authorization for research subjects. A *separate* HIPAA authorization must be obtained for both *clinical care* and *research activities*. These authorizations are required under the federal regulations! If you have inadvertently made this error, please report it immediately to the Children's IRB.

RESEARCH-SPECIFIC HR RESOURCE COMING SOON

The Research Oversight Committee has approved the creation of an HR liaison position within Research Operations. This new position will provide a resource for faculty seeking to hire research staff and will ensure more timely posting and hiring decisions.

WATCH YOUR EMAIL FOR GRANT OPPORTUNITIES

OSR will be emailing a weekly grant opportunities report from NACHRI to investigators. To be included on this e-mail list, please contact your SPO.

Nguyen Ascends Mt. Rainer

Congratulations to Dao Nguyen (Burns' lab at 307 Westlake), who successfully reached the summit of Mt. Rainier (14,410 feet) on Monday, July 18th at 8:30 a.m. Dao's victory over Mt. Rainer benefited the **American Lung Association® of Washington** to the tune of \$4,756.00. "After a failed attempt on July 8th because of unusually stormy weather, this climb was blessed with the best conditions possible. It was one of the most exhilarating and wonderful experiences I have ever had. Thank you for all of your support" said Nguyen.

The American Lung Association of Washington works to:

- Help kids with asthma live full and productive lives.
- Stem the tide of Big Tobacco money that is urging young people to start a lifelong habit that takes the lives of 8,200 Washingtonians every year.
- Fund research to find cures for lung cancer, emphysema, pulmonary fibrosis, tuberculosis, and lung disease of all kinds.
- Advocate for clean air in our beautiful state.



Dao Nguyen, M.D. at the summit of Mt. Rainer

Q&A on IDCs

What is the difference between "F&A" and "Indirect Costs"?

These terms are used interchangeably, although the federal government prefers "F&A", which stands for facility and administrative costs.

Why doesn't Children's return a portion of its indirect costs to the faculty like the University of Washington?

The University of Washington uses a decentralized research administration system, which is typical of most large universities. Although there is a central Office of Sponsored Research, most pre- and post-award grant activity is provided at the departmental level. To support this activity, the University distributes a portion of its recovered indirect costs to the department. Many departments choose to return a small percentage of these "indirect dollars" to the faculty as an incentive.

In contrast, Children's uses a centralized research administration system, which is typical of smaller institutions. Indirect costs are treated as "revenue" to the research enterprise, and cover roughly 50% of our actual facility and administrative costs. Rather than provide individual incentives, Children's budgets approximately \$1 million annually for intramural programs such as our Young Investigator Awards and Steering Committee Awards.



What is the difference between "off-site" and "on-site" rates?

The terms "on-site" and "off-site" are used in our clinical F&A rate to describe the location of the research activity. The "on-site" rate includes Children's facility costs and the "off-site" rate does not. Typically, research conducted "off-site" includes rent (or a facility use fee) as a direct expense to the grant.

When do I use the newly negotiated F&A rates?

All proposals subject to the federally negotiated rates that are currently being prepared for submittal are to include the new indirect cost rates, with the clarifications noted below:

Existing awards. Indirect cost rates for existing awarded projects will not be increased to the new rates until such time as a proposal is submitted for future funding.

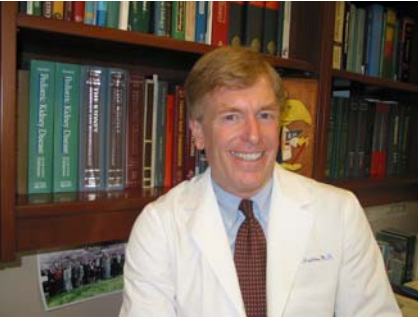
Pending (already submitted) proposals for NIH grants. *Competing Proposals (New, Renewal, Resubmissions.)* A revised checklist reflecting the new indirect cost rates and amounts will be prepared by OSR with the other "Just-in-Time" documentation requested by the NIH. This will not impact PIs/projects since NIH is unique in that it is the only agency that awards indirect costs from a separate pool, thereby not impacting the direct costs. *Supplements.* Will be accepted at the rate submitted unless NIH provides an opportunity to update the proposal. For future, not yet submitted supplements, the new rates will be requested. *Non-Competing Proposals (Continuations.)* Includes pending or future continuation proposals for existing grants. Since the indirect cost allocation/rate for NIH continuation funding is already established with the initial award, the rates will not change for continuation funding for ongoing projects.

Pending (already submitted) proposals for all other federal funding agencies or non-federal agencies using the federally negotiated rates. Proposals that have already been submitted are only to include the new indirect cost rates if the agency asks for the submittal of a revised budget. If a revised budget is requested, and if the project is restricted to a bottom line/maximum amount, the increased rates will not be used if such use would impact the already proposed direct costs for the project. The PI will be asked to provide a brief justification to OSR as to how the proposed direct costs would be impacted if the new indirect cost rates were used.



South Lake Union Block Party at Westlake and Denny

This year's event will be bigger than ever and will feature a main stage, beer and wine garden, children's play area, scooter test drive arena, food sampling and vending area, artisan booths and an "Iron Chef" competition. Children's Hospital will again host a booth at this event, showcasing Children's pediatric research activities in a kid-friendly manner. **When:** Friday, September 16, 3:00 p.m. - 8:00 p.m. and Saturday, September 17, 11:00 a.m. - 4:00 p.m.

from the desk of the Pediatrician-in-Chief:

Pediatric research supported by Children's Hospital extends well beyond any boundaries framed by bricks and mortar. Children's Hospital, UW Medicine and the Fred Hutchinson Cancer Research Center share a common pediatric research vision. The strategic alignment of these organizations is critical to our long-term success. Phase I of our Strategic Plan to Advance Research at Children's (SPARC) identified several key areas for strategic thinking. Before moving into SPARC Phase II, we have initiated formal discussions with our partners in an effort to align priorities. These critical steps will ensure the long-term success of our strategic planning.

While a formal strategic plan is critical to guide and measure progress, rest assured that during this planning phase we will continue to move forward strategically. The Research Oversight Committee (ROC) meets monthly to review progress and plan for the future. ROC

Dr. Stapleton Reassures Progress Will Not Lag

members assess financial performance, space allocation, operations performance, and funding productivity. The ROC is regularly updated and provides advice on a range of issues, from vivarium capacity to recruitment prospects. The ROC also provides a sounding board for issues presented by the three enterprise Steering Committees. These Steering Committees are responsible for raising logistical issues that impact basic, clinical, or outcomes researchers. The Steering Committees also administer intramural funds, including the Young Investigator Award Program and the Steering Committee

"...rest assured that during this planning phase we will continue to move forward strategically"

Award Program. Both of these programs have been hugely successful in their first year thanks to the tireless work of these committees.

I encourage all pediatric research faculty to communicate issues and concerns to our steering committee chairs:

Basic Science—Craig Rubens
Clinical Research—Bonnie Ramsey
Outcomes Research—Fred Rivara

Soon we will begin a new fiscal year at Children's Hospital; with it comes a new President & CEO. I am delighted that Dr. Tom Hansen has accepted this important position. Dr. Hansen was most recently CEO at Columbus Children's Hospital and Chairman of the Department of Pediatrics at Ohio State University. If you haven't done so already, I encourage you to visit the Columbus Children's Hospital web site to learn about their successful programs (www.columbuschildrens.org). Dr. Hansen shares our research vision and will work closely with the research leadership to build on our current success. I am confident that Tom will be impressed with the productivity and resourcefulness of our researchers.

F. Bruder Stapleton, M.D.
Professor and Chairman
Department of Pediatrics
Pediatrician-in-Chief

Research Staff CE/Travel Fund to be Created

Jim Hendricks, *VP, Research*, recently announced plans to create a research staff continuing education (CE) and travel fund. The fund, to be seeded with \$20,000 next fiscal year, will make awards to research staff (e.g., technicians, technologists, CRAs, SPOs, etc.) to attend regional and national meetings. Details of funds management and distribution will be determined by a Staff Advisory Group. One prerequisite for funding will be active participation by the staff member in a poster, platform,

or similar presentation of data/information. "The research staff travel fund will provide an equal opportunity for all staff to advance both their knowl-



edge and the research vision of Children's Hospital," said Hendricks. A request for proposals is expected to be issued sometime in November. Now is the time to meet with your PI, manager, or director to discuss opportunities for presenting data. RSS staff should consider reporting on the effectiveness of Continuous Performance Improvement (CPI) activities in their respective departments.

IRB Statistics

IRB statistics for the period 1/1/05 to 7/31/05 were recently compiled, and are shown in the Table below. Turnaround time (TAT) for full IRB reviews was 85.7 ± 46.5 days (range 14-177 days), compared to 69.9 ± 49.5 days for the same period last year. Turnaround times for expedited IRB reviews was 36.1 ± 29.1 (range 5-122 days), compared to 29.3 ± 23 days for the prior period.

Measure	Value
# Full Approvals	53
Avg. TAT Full Approvals	83.7 ± 46.5 days
Range TAT Full Approvals	14—177 days
# Expedited Approvals	31
Avg. TAT Expedited Approvals	36.1 ± 29.1 days
Range TAT Expedited	5—122 days

The IRB uses a “checkpoint monitoring system” to measure continuous flow through the IRB process. The system, employed as a Continuous Performance Improvement measure, breaks down the IRB approval process into six (6) temporal intervals as follows:

- A. Date of application receipt to date pre-review complete;
- B. Date pre-review complete to IRB meeting date;
- C. Date of IRB meeting to date of formal PI notification of findings (i.e., contingency, approval, deferral letter);
- D. Date of PI notification to date of receipt of formal response from PI;
- E. Date of receipt of formal response to date IRB findings are considered met/resolved;
- F. Date IRB findings considered met/resolved to date IRB Chair signs approval letter.

Figure 1 shows checkpoint statistics for calendar years 2004 and 2005. As you can see, intervals A and D contribute the most to the total turnaround time. Elizabeth Trias, Manager of the IRB states, “I am pleased to report that despite the fact that the IRB reduced its total workforce by 1 FTE, there has been no significant change in TAT statistics. Credit for this goes to my staff who work tirelessly on behalf of research participants and investigators. I applaud my staff for their Herculean efforts.” The IRB Staff includes:

Esther Kohler
 Kelly Culbert
 Sue Amott

IRB Full Review - Checkpoint Summary

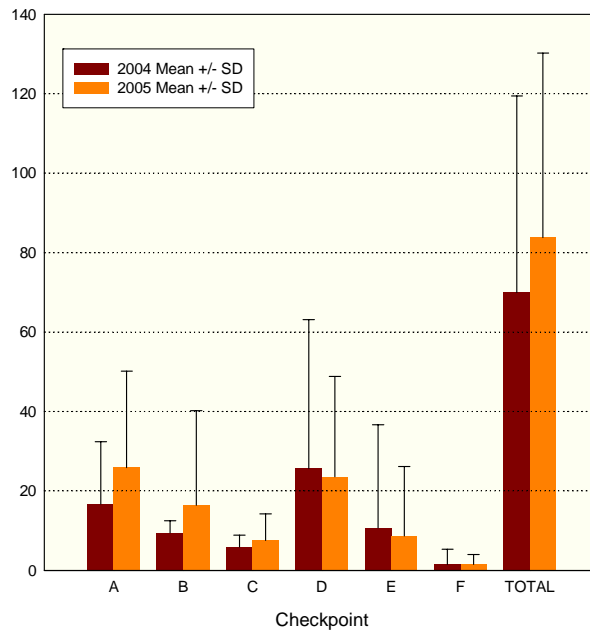


Figure 1. Checkpoint Monitoring System

DON'T MISS "JIVIN' WITH JIM"

Bring operational issues to this monthly brown bag luncheon with Jim Hendricks, VP, Research. Brought to you every Tuesday from 11:30 a.m. - 1:00 p.m. at Westlake or MPW:



- First Tuesday
- Second Tuesday
- Third Tuesday
- Fourth Tuesday

- Westlake Staff
- Westlake Faculty
- MPW Staff
- MPW Faculty

Research Bits & Pieces

Research Web Site to be Launched in November

Children's Marketing & Communications Department has been working closely with the Research Oversight Committee on the design and content of a research web site. The new site will feature research news, research jobs, an investigator finder, and links to Research Support Services (RSS) Departments. RSS Department-specific pages will provide links to policies and commonly used forms. The anticipated launch date is early November 2005.

Children's to Recruit Director, Office of Institutional Assurances

A search committee has been formed to recruit a Director, Office of Institutional Assurances (OIA). This new position will be responsible for directing and implementing a compliance plan for research, providing direction, guidance, and supervision for all staff, and managing all related budgets. This includes development of policies and procedures, an auditing and enforcement process, and a comprehensive communication and training program. The position, reporting to the VP, Research, will supervise managers of the Institutional Review Board, Institutional Animal Care and Use Committee, Institutional Biosafety Committee, and Research Regulatory Affairs.

The OIA Director Search Committee, chaired by Dr. Elizabeth McCauley, includes representatives of the faculty and staff. The search process will begin in early September with the goal of filling this important position by next spring.

TDN Relocates to MPW

The Therapeutics Development Network (TDN) relocated from Lake City to the 5th floor at MPW on August 19, 2005. This move brings the 5th floor to near capacity, growing Children's presence at MPW to approximately one

hundred twenty people. Other groups on the floor include the Office of Biostatistical Services, Institutional Review Board, Office of Research Finance & Sponsored Projects, Center for Children with Special Needs, Research Project Management, and Continuous Performance Improvement. MPW welcomes the TDN!

Open House at MPW

MPW will be hosting an open house for Children's employees and affiliates on Thursday, September 29th from 9:30 a.m. until 12:30 p.m. Research staff from Westlake and 8P are invited to tour.

Practical Aspects of Conducting Pediatric Clinical Trials

Mark your calendar! The Office of Clinical Research (OCR) and the Pediatric Clinical Research Center (PCRC) bring you the 4th annual "Practical Aspects of Conducting Pediatric Clinical Trials." These lectures will take place from 12:00 noon to 3:30 p.m. in the Hospital's Wright Auditorium on the following Mondays: October 3rd, 17th, and 24th. A light lunch and lecture materials will be provided. During these sessions, speakers will present topics in the categories of Consent/Assent, Fiscal Issues, and Compliance related to conducting human subject research here at Children's. These lectures are open to all Investigators and Clinical Research Staff.

Research Coordination 101

The 2nd annual "Research Coordination 101" will also take place this fall. This workshop series is oriented to new Clinical Research Staff at Children's. A continental breakfast will be provided. This series will take place on the following Tuesdays: October 4th from 9:30 a.m. to 12:00 noon in G1027; and October 18th & 25th from 9:30 a.m. to 11:30 a.m. in G1026.

Ezell's Chicken to Make Appearance at MPW and Westlake

Children's Annual Employee Picnic is scheduled for Wednesday, September 14th for the Hospital and off-site locations, including MPW and 307 Westlake. There will be vegetarian and fried chicken entrée options as well as side dishes. Similar to previous years, the food will be set up in a central area at each location. Details will be provided as the event nears.

Clinical Research Staff Celebrates First Quarter at MPW

It has been almost four months since the Clinical Research Staff moved from the Children's Hospital main campus to their new downtown location on the 8th floor of MPW. Despite some relocation challenges, staff are settling in and beginning to enjoy the numerous amenities that downtown Seattle and MPW have to offer.

"Met Park West is within walking distance to the SCCA, where I see the majority of my patients. Plus, I get forty minutes more exercise per day," says Amanda Allpress, Clinical Research Associate, Infectious Disease. "I enjoy the downtown location and quiet work environment," said Alan Genatossio R.N., Research Nurse Coordinator, Cystic Fibrosis Research.

Equipment SUPERUSERS at Westlake

Each piece of shared lab equipment at 307 Westlake has been assigned a "superuser" by a related-department Principal Investigator (PI). A superuser's role is to insure proper care and instruction related to their assigned piece of equipment. A list of superusers may be found on the network shared drive 'ResearchAppr on S220' in the '307Info' folder. If you have any questions regarding this, please contact Lisa Cook.

Staff Matters Issues of Interest to Research Staff

MPW Elevator Upgrade Nears End

MPW is nearing the end of a large elevator upgrade project that aims to reduce crowded elevators while speeding up access times by grouping like destinations together. Rather than waiting for an elevator, getting in, and pressing the button of your destination floor, tenants and visitors will select the floor at a kiosk in the elevator lobby. The kiosk will group like destinations and direct people to specific elevators. On secured floors, where key cards are required for access, individuals will use the same kiosk system and swipe their key card in front of the key card reader as they enter the elevator. All elevators should be back in service by early September, with the kiosks in operation by November. MPW and Park Place, also a Benaroya-owned property, are the first two buildings to implement this kind of "smart elevator" system in the State of Washington.

Downtown Streets and Bus Routes Affected by Tunnel Closure

On September 24, 2005, the bus tunnel under downtown Seattle will close for two years for light rail retrofitting and utility upgrades. All tunnel bus routes will be converted to surface street routes, creating a domino effect of impacts on bus commuters as well as drivers on downtown streets.

Routes Moving From Tunnel to Surface Streets	
Routes	Relocating to
41, 71, 72, 73, 101, 106, 150 & 301	3rd Ave in both directions
177, 190, 194, 196, 212, 225, 229 & ST 550	2nd Ave southbound & 4th Ave northbound
255, 256 & 266	4th Ave northbound & 5th Ave southbound
306 & 312	3rd Ave northbound & 2nd Ave southbound
* Check your route(s) for final configurations in September.	

In addition to relocating tunnel routes to surface streets, several current surface-level bus routes will be relocated to other streets, allowing Metro to group buses with common destinations. For example, routes 26, 28, 34, 39, 42, 160, & 163 will move from their current 2nd & 4th Avenue routings to 3rd Avenue. Other impacts on bus commuters will include fewer stops on some routes in order to improve commute times.

Non-bus traffic will also see impacts on downtown streets. During the morning and afternoon commute periods, 3rd Avenue, between Stewart Street and Yesler Way, will be converted to a transit-priority corridor.

Lab Coat Laundering

Staff at Westlake and MPW may send lab coats to the Hospital with the daily courier for cleaning. To avoid long wait times and lost coats, please complete **one Linen Form for each lab coat to be laundered**, secure the form to the coat, and bring to the front desk at your respective locations. Expected turnaround time for laundering is five to seven working days. Linen Forms may be obtained by contacting Michael Gordon in the Linen Department of Central Services.



Learn more about Continuous Performance Improvement Activities at Children's Hospital! Visit the CPI Department web site on CHILD at <http://child/departments/cpi/>

from the desk of the **Vice President for Research**



In an effort to enhance communication within the Research Division, I am pleased to present this inaugural issue of *interaction*. This monthly newsletter aims to provide information on a variety of topics of interest to the research community. Topics range from changes in our negotiated F&A rate to plans for implementation of clinical trial software (Study Manager®). If you have an issue that you would like to see addressed in *interaction*, contact Heather Lindemann.

Every Tuesday I host a brown-bag lunch, aptly titled "Jivin' with Jim". These "town hall" style meetings provide an opportunity to discuss any issue/concern (large or small). I encourage you to drop in anytime between 11:30 a.m. and 1:00 p.m. as follows:

First Tuesday
Westlake Staff

Second Tuesday
Westlake Faculty

Third Tuesday
MPW Staff

Fourth Tuesday
MPW Faculty

As you know, Children's recently implemented an Enterprise Resource Planning (ERP) system. It is well known in the industry that ERP implementation can be a painful process. This has certainly been the case for the Research Division. In order to address ERP problems and concerns in an open and productive manner, an ERP Faculty Advisory Group has been formed. This

group meets monthly with management to review implementation progress and recommend action items. The ERP Faculty Advisory Group includes:

James Bassuk, Ph.D.

Amanda Jones, Ph.D.

David Rawlings, M.D.

Bruder Stapleton, M.D.

Danielle Zerr, M.D.

Finally, I wish to congratulate the Pediatric Bioethics Conference Planning Committee for a stellar event. Special kudos to Dr. Doug Diekema, Laurie Bolton, Heather Lindemann, Nanci Villareale, and Kathie Kohorn!

-Jim Hendricks

Specimen Processing Core Available

Open since November 2004, the Specimen Processing Core (under the Office of Clinical Research) is a resource for the processing, storage, and shipping of research diagnostic specimens. This Core has dedicated bench space on the 8th floor of the Children's Hospital Pavilion and is staffed with a full-time specimen coordinator.

The Specimen Processing Core provides the following services:

- Specimen processing and shipping support, education, and training;
- Research Specimen Transport System (transports research samples from the inpatient floor and

ambulatory clinics to the Main Clinical Lab for pick-up by the OCR-SPL coordinator);

- Dedicated bench space for specimen processing;
- General specimen processing supplies: 1) Dry Ice; and 2) Shipping containers, labels, tape, and related packing supplies/materials;
- Diagnostic sample processing equipment: 1) Refrigerated centrifuge; 2) Desktop clinical centrifuge; 3) Freezers (-20C and -80C); and 4) Refrigerator.

For more information about accessing these Core Services, call Christine Phillips at 7-1875 or page her at 469-6358.



IRB NEWS BRIEFS FROM THE IRB

IRB Policies and Information Sheets Available on the Web

Ever wonder which IRB form to use?

What are the IRB policies related to using private medical records in research?

What are the IRB fees?

Informed consent or assent: What do I need to do as a researcher?

How do I properly obtain consent from families with limited English skills?

How can I appropriately involve children that are wards of the state in research?

How should we handle research-related injuries?

<http://irb.seattlechildrens.org/>

Over 80% of applications submitted to the IRB are incomplete.

In the day-to-day operations this means that IRB staff are forced to spend time completing applications and hunting down missing information. "A significant amount of time is wasted that could be used more effectively on value-added services," said Erik Lausund, *Chief of Research Operations*. Utilizing Continuous Performance Improvement (CPI) principles, the IRB staff is working to refine its pre-review process. As the data on page 5 of this issue demonstrates, the IRB averages more than 20 days on pre-review of each new protocol. Much of this time is focused on completing the application materials. In a majority of cases, con-

sent or assent documents are incomplete or missing altogether. "Improving the pre-review process in an effort to promote continuous flow will require that investigators submit complete applications," says Jim Hendricks, *VP, Research*. "I have advised the IRB to return applications that are incomplete in an effort to focus work on the timely review of completed applications."

Software Purchased to Ensure Research Billing Compliance



The University of Washington Medical School and the Seattle Cancer Care Alliance (SCCA) have issued a policy that includes uniform requirements for the billing of professional and technical services provided at all sites of practice, including Harborview Medical Center (HMC), University of Washington Medi-

cal Center (UWMC), Seattle Cancer Care Alliance (SCCA), and Children's Hospital and Regional Medical Center (CHRMC). In addition to the sites of practice, this policy encompasses the practice plans of University of Washington Physicians (UWP) and Children's University Medical Group (CUMG.) The new policy, Policy 1.0, is applicable to all services regardless of funding source.

In order to meet the requirements set forth in this policy, a project team has been developed within our research enterprise to facilitate the technical, systems, process, training, and change management needed. This project team has collaborated with the Clinical Research Steering Committee about this systems change as well as the new software tool, **Study Manager**®. A product from Advanced Clinical Software (ACS), **Study Manager**® will manage patient flow in order to establish appropriate budgets and will generate a documentation trail to help ensure compliance.

Although this is a mandatory change the project team's mission is to incorporate faculty, staff, and administrative input in this process. "We realize this is going to be a big change; however, we must take action. We will work closely with a variety of groups within the Hospital to make this as painless as possible," said Pam Joy, *Director of the Office of Clinical Research*.

Watch for additional information and project updates in the months to come. The project is still in the formation phase and plans are not yet solidified. The official launch is planned for 2006. Questions or concerns? Please contact Pam Joy.

To access the UW Medicine Clinical Research Budget and Billing Support Office (CRBB), visit <http://www.uwmedicine.org/Research/ResearchBudgetBilling/CRBB+Home.htm>

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Children's
Hospital & Regional Medical Center

A publication of the
Research Division



Treuman Katz, President and CEO of Children's Hospital, and Keynote Speaker Dr. Albert Jonsen, Emeritus Professor of the University of Washington School of Medicine.

First Pediatric Bioethics Conference a GREAT Success

A capacity crowd of more than 200 professionals from across the nation attended the first annual conference on pediatric research ethics hosted by Children's Center for Pediatric Bioethics on July 22-23, 2005 at the downtown Seattle Red Lion Hotel. The event, entitled *Current Controversies in Pediatric Research Ethics*, was highlighted by both local and national media.

The conference focused on some of the most controversial issues in pediatric research today, including whether the current federal regulations that govern such research should be revised, what influence industry and industry funding has on research, and how and when children should participate in research. "By addressing the complex ethical issues that affect patients, families, healthcare institutions, and research involving children, we hope the conference results will aid in promoting the highest standards of medical ethics and protections of patient rights in pediatric research and healthcare," said Treuman

Katz, President and CEO at Children's Hospital.

Several internationally-recognized authorities in the fields of medical and research bioethics rounded out the two-day agenda.

"The dynamic interchange between some of the country's leading medical thought leaders, clinical ethicists, and Children's faculty, with an audience of international advocates for children was inspiring as well as informative. The conference demonstrated our Center for Pediatric Bioethics as a national



Drs. Robert ("Skip") Nelson, Eric Kodish, and Norm Fost take part in a panel discussion at this year's conference.

resource and discussions there will certainly influence our research policies. Our goal is to ensure the rights and protection of children who participate in research studies," said Dr. Bruder Stapleton, Pediatrician-in-Chief and conference planning committee member. Dr. Jim Hendricks, Vice President, Research and conference planning committee member said, "The Center for Pediatric Bioethics is an integral part of Children's commitment to the highest ethical standards in clinical care, education, research, and advocacy. The Center's first, of what will be an annual meeting, provides a vehicle for taking this commitment beyond the walls of our own institution in an effort to promote policies and advocate best practices and standards on a national and international level."

Children's Center for Pediatric Bioethics is the nation's first center for bioethics dedicated solely to the study of research and healthcare for children.