Note from Director

Our pediatric research activities are central toward achieving our mission of providing the best care and treatments to children across Advocate Children’s Hospital (ACH). In that vein, our pediatric research portfolio includes independent investigator-initiated research conducted by ACH investigators, clinical trials of new medications and devices sponsored by industry, as well as collaborative studies with investigators at universities and other children’s hospitals. This issue of Insights highlights just some of this research which involves multiple disciplines and clinical sites, and illustrates our commitment towards advancing the care of children and families we serve.

Denise B. Angst, PhD, RN
Director, Advocate Center for Pediatric Research

Clinical Research News

Evaluating a Medication Combination in Cystic Fibrosis Patients

Researchers at Advocate Children’s Hospital are participating in two exciting new clinical trials looking at the safety and effects of two medications, lumacaftor and ivacaftor, for the treatment of cystic fibrosis (CF) in patients who are homozygous for the most common CF mutation (F508del-CFTR). Both medications are designed to treat the underlying cause of CF, a faulty gene and its protein product, CFTR. The F508del mutation creates a defective protein that does not move to its proper place at the cell surface. Lumacaftor is designed to move the defective protein to the cell surface; Ivacaftor acts by improving the protein’s function once it reaches the cell surface. Results from an earlier Phase 2 clinical trial of these medications showed significant improvements in lung function in people with two copies of the F508del-CFTR mutation. The study will involve about 500 patients across CF Centers in the United States. The Principal Investigators are Javeed Akhter, MD (Oak Lawn campus) and Arvey Stone, MD (Park Ridge campus).
Spotlight on Investigator-Initiated Research

Physician-led Research
Drs. Aljadeff, Watts, and Stone of the Cystic Fibrosis Center at Advocate Children’s Hospital – Park Ridge and Advocate Lutheran General Hospital are collaborating with Rosalind Franklin University, Chicago Medical School on a study developing methods to test the medicine ivacaftor on nasal cells of individuals with cystic fibrosis (CF). The study will evaluate how patients respond to ivacaftor and other similar medications that aim to treat the basic defect of CF. Cells will be collected by nasal brushing and tested for their response to the medications. In addition, a blood sample obtained by finger prick will be sent to Genzyme labs for full genetic sequencing. Information from this study will hopefully lead to a national resource for CF drug discovery and patient treatment.

For more information, please contact Suellen Moen, RN, CF research coordinator, at 847-738-7334.

Nurse-led Research
Dr. Denise Angst is leading a new collaborative study with Dr. Nancy Ryan-Wenger at Nationwide Children’s Hospital. Two patient care units at Advocate Children’s Hospital- Oak Lawn (ACH-OL) are looking at pediatric patients’ perceptions of their hospital experience using a “6th Vital Sign” questionnaire. The questionnaire includes questions about children’s experiences with the nursing care they receive. Eligible subjects from ACH-OL are randomized to one of 3 groups: (1) receive usual care from nurses, (2) receive usual care plus complete the 6th Vital Sign questionnaire, or (3) receive usual care, complete the questionnaire and have the child’s results shared with his/ her nurse. Data is also collected on the child’s demographics and perceived quality of life, to examine differences in children’s perceptions of their nursing care by age group, gender, diagnosis, length of stay, and other variables.

For more information, please contact Mary Murray, RN, ACH-OL research coordinator, at 708-684-4576.

Upcoming Educational Opportunities

UIC CCTS - Summer Program in Clinical and Translational Research Methods, July 9-11, 2013
• This is a 3-day program in clinical and translational research methods for clinicians interested in incorporating research into their clinical practice and others who are interested in exploring clinical and translational research possibilities. Content will include research methods, identifying the steps required for conducting clinical research, online bibliographic citation management software and the ethical considerations of clinical research, including requisite IRB approval and HIPAA requirements.
• Registration deadline is June 14, 2013 and space is limited.
• For more information, please contact Birute Petrauskas at birutep@uic.edu or 312.413.5429

• The CRC on-line training features an on-line classroom where participants meet weekly to learn the role of a clinical research coordinator and the basics of clinical research. The course content is designed to provide a practical introduction to the CRC role and includes an overview of the clinical research process, an introduction to roles of key personnel involved in clinical research, good clinical practice, ethics, regulatory considerations and best practices for success in this position. The 2013 new and improved course contains updated content, interactive online exercises, and an analytic case study component that is followed throughout the course to facilitate a higher level of learning and comprehension.
• Participants must complete a free 30-minute prerequisite course. Summer session begins July 11 for 5 weeks. The class meets every Thursday, 1:00-3:00pm, July 11-Aug 8.
• Cost is $499
• For questions, please call 312.503.7952
• Additional information is available: http://www.nucats.northwestern.edu/education-career-development/research-support-staff-training/clinical-research-coordinator-basic-training/crc-basic-training-online.html

For more information on research with children at Advocate’s Children’s Hospitals, visit www.advocatehealth.com/pedsresearch
When is QI Considered Research?

The volume of quality improvement (QI) activities within health care has grown in recent years consistent with the evolution of health care organizations into learning systems where clinicians collect, aggregate, analyze and learn from their practices and outcomes.\(^1\) Yet, determining when a QI project is considered research warranting Institutional Review Board (IRB) review and approval can be confusing for clinicians and teams. Adding to this confusion is the fact that Federal regulations\(^2\) do not specifically distinguish QI from research. As such, there can be variability between institutions and IRBs on which QI activities require IRB review. The purpose of this article is to clarify how this determination is made using definitions in the Federal regulations and what do if you still have questions about your project.

The goal of quality improvement centers on translating evidence or existing knowledge into clinical practice in order to improve the quality of care and health outcomes within a local institution or health care setting.\(^3,4\) QI projects employ systematic data gathering and evaluation, and often involve a practice change or intervention that is further studied for its impact on care practices or patient outcomes. Methods commonly used in QI projects include Six Sigma\(^5\) or the Plan-Do-Study-Act (PDSA) cycle.\(^6\)

Although QI projects often involve systematic methods, patients or participants, and evaluation and dissemination of project results, the majority of QI projects do not require IRB review. In order to determine the need for IRB review, it is important to ask two key questions, using the terms defined by the Federal regulations:

1) Does the project qualify as “research”?
2) Does the project involve “human subjects”?

The Federal Regulations define:

- **Research** as “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge” [45 CFR 46102(d)], and

- **Human subject** as “a living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual, or (2) obtains identifiable private information” [45 CFR 46.102(f)].

Although there is no absolute litmus test to distinguish research from QI, the definitions provided by Federal regulations allow clinicians and teams to determine whether their work is likely to require IRB review. For example, given these definitions, a case study would not require IRB review, nor would a QI project that does not collect patient identifiers. Another helpful tool to use is the accompanying checklist developed by the Yale University IRB.

In the end, if you still have questions after looking at the definitions and checklist, you should contact the Advocate IRB office for a final determination. You can contact the IRB by calling 630.929.6148 or sending an e-mail with a brief description of your project to joal.hill@advocatehealth.com.

---

Quality Improvement or Research Checklist*

If all of the questions below can be answered as a Yes, IRB review is not required. If the answer to any of these questions is NO, please consult with the IRB for assistance since IRB review may be required.

<table>
<thead>
<tr>
<th>Project Description</th>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Purpose</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is the activity intended to improve the process/delivery of care while decreasing inefficiencies within a specific health care setting?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Scope</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is the activity intended to evaluate current practice and/or attempt to improve it based upon existing knowledge?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Evidence</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is there sufficient existing evidence to support implementing this activity to create practice change?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clinicians/Staff</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is the activity conducted by clinicians and staff who provide care or are responsible for the practice change in the institutions where the activity will take place?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Methods</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Are the methods for the activity flexible and include approaches to evaluate rapid and incremental changes?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sample/Population</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Will the activity involve a sample of the population (patients/participants) ordinarily seen in the institution where the activity will take place?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Consent</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Will the planned activity only require consent that is already obtained in clinical practice, and could the activity be considered part of the usual care?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Benefits</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Will current patients/participants at the institution where the planned activity will be implemented potentially benefit from the project?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Risk</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is the risk to patients/participants no greater than what is involved in the care they are already receiving OR can participating in the activity be considered acceptable or ordinarily expected when practice changes are implemented within a health care environment?</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Developed by Yale University IRB and adapted by Duke University IRB, March 2013

** Mark your Calendars **

** 2013 Achieving Excellence in Clinical Research Conference **

SAVE THE DATE for the 2013 conference to be held Friday, September 20th at McDonald’s Hamburger University. Exciting keynote speakers to include:

- **The Research–Treatment Distinction: A Problematic Approach for Today’s Learning Health Care Systems** Tom Beauchamp, PhD, Senior Research Scholar, Kennedy Institute of Ethics; Professor of Philosophy, Georgetown University; Co-author of Belmont Report
- **Is Equipoise Necessary for Ethical Clinical Trials?** Steven Joffe, MD, MPH, Emmanuel & Robert Hart Professor of Medical Ethics and Health Policy, Department of Medical Ethics and Health Policy, University of Pennsylvania, Perelman School of Medicine
- **From Lost in Translation to Implementation in Practice...Making Research Visible** Nancy Fugate Woods, PhD, RN, FAAN, Professor, Biobehavioral Nursing, and Dean Emeritus, University of Washington School of Nursing

Along with a variety of great afternoon breakout sessions. … So don’t miss out!

For more information, visit our website at www.advocatehealth.com/pedsresearch or call 847.723.2164. The conference brochure and registration will be available in late June.

For more information on research with children at Advocate’s Children’s Hospitals, visit www.advocatehealth.com/pedsresearch