Human Research Newsletter

FEBRUARY 25, 2015 VOLUME 1, NUMBER 1

Welcome to our first issue!

As part of our work to provide ongoing education for research study team members we are introducing the Human Research Newsletter!

The purpose of this newsletter is to promote communication and guidance on conducting human research at Children's Hospital of Wisconsin in accordance with ethical standards and applicable regulations.

We will highlight important new information, recurring issues, and a variety of other significant topics. Examples include updates from regulatory agencies, compliance information, and tips from the IRB.

Thank you for taking the time to read through this newsletter. Should you have any questions, concerns, or ideas for future topics, do not hesitate to contact us!

IRB Office updates

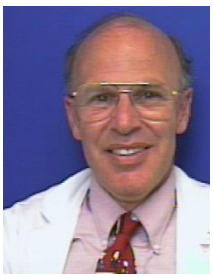
Derek Jirovec and Julia Kennedy recently joined Lori Mroczek in staffing the IRB Office. Please contact us with any questions!

Lori Mroczek, Lead IRB Coordinator, IRB#1
lmroczek@chw.org 414-266-2986

Derek Jirovec, BS, IRB Coordinator, IRB#2
djirovec@chw.org 414-337-7133

Julia Kennedy, MPA, CIP, Research Integrity Manager
jkennedy@chw.org 414-337-7705

IRB#2 Chair update



After many years of serving on CHW IRBs and as Chair for IRB#2, Dr. Robert Schum has retired.

Effective January 1, Dr. Bruce Camitta was appointed interim Chair of IRB#2. Dr. Camitta has served on CHW IRBs since 1979 and has also been a Co-Chair on IRB#2.

INSIDE THIS ISSUE:

Pediatric Translational Research Unit

The Pediatric TRU is a unique unit within the Hospital here to supplement your current research infrastructure. We are located on Center 4 South and are open Monday-Thursday from 0730-1630; Fridays 0730-1600; and offer extended hours on Tuesdays until 1800. Additional requests for services outside these times can be discussed with Beth Gissibl Pediatric TRU Manager.

The TRU provides a variety of services, including:

- Research Coordination Support (consultation, navigation, and guidance)
- Nursing support (All RNs are PALS certified nurses)
- Phlebotomy and IV starts
- 12 Lead EKG support (not reading/interpreting)
- Lab spinning and storing of serum, plasma, buffy coat; ability to draw clinical labs at time of the research draw; obtain DNA samples for pick up and processing
- Specimen shipping – IATA/DOT trained
- Dedicated exam rooms for study participants
- Investigation drug administration
- Bod Pod and Pea Pod for body composition measurement
- Ambulatory BP Monitoring equipment available for TRU supported studies
- Data Entry (REDCap)

The TRU provides a variety of support for both funded and unfunded research. If you wish to initiate a study using the TRU or want to learn more about how we can meet your needs, please contact: Beth Gissibl @ 266-3994 and/or Jeff Crawford @ 266-7254 (TRU Research Coordinator).

Regulatory News

Newborn Screening Research Using Dried Blood Spots

Congress enacted the Newborn Screening Saves Lives Reauthorization Act of 2014 on December 28, 2014. Quietly buried at the end of this new law is a section that directly affects human subjects regulations. Note that the elements about blood spots apply only to blood spots collected on or after March 26, 2015.

- Section 12.a: Requires federally funded research on newborn dried blood spots to be considered research on human subjects (which requires informed consent).
- Section 12.a: Eliminates the ability of an institutional review board to waive informed consent requirements for research on newborn dried blood spots.
- Section 12.c: Requires HHS to release a Notice of Proposed Rulemaking describing the proposed changes to the Common Rule, no later than six months (June 29, 2015) after the enactment of this Act.
- Section 12.c**:** Requires HHS to implement the changes to the Common Rule no later than two years (December 28, 2016) after enactment of this Act.

A summary of the law is available online at:
https://www.congress.gov/bill/113th-congress/house-bill/1281/all-info

Draft FDA Guidance Explains how to Test Drugs on Pediatric Patients

The FDA released draft guidance for industry titled "General Clinical Pharmacology Considerations for Pediatric Studies for Drugs and Biological Products." The draft guidance is intended to assist those sponsors of new drug & biologic applications who are planning to conduct clinical studies in pediatric populations. It addresses general clinical pharmacology considerations for conducting studies so that the dosing and safety information for drugs and biologic products can be sufficiently characterized, leading to well-designed trials to evaluate effectiveness. **Section IV. "Ethical Considerations" contains specific guidance for IRBs when assessing additional safeguards for children under Subpart D (see pages numbered 7-10).**

Draft OHRP Guidance on Appropriate Disclosure of Risks in Research Evaluating Standards of Care

In October 2014, the Office for Human Research Protections (OHRP) released a draft guidance document titled "Guidance on Disclosing Reasonably Foreseeable Risks in Research Evaluating Standards of Care."

At the recent 2014 Advancing Ethical Research Conference presenters from OHRP explored the issue of disclosing reasonably foreseeable risks to prospective subjects in studies about standard of care treatments and reviewed their draft guidance. A video recording of this session can be accessed online at http://primr.blogspot.com/2014/12/ohrp-discusses-draft-guidance-on.html.

Public Responsibility in Medicine & Research (PRIM&R) submitted comments to OHRP expressing concern about the narrowness of the draft guidance's scope. PRIM&R urges OHRP to rewrite the document to provide clearer guidance to investigators, IRBs, and sponsors and puts forward several recommendations for future guidance.
http://www.primr.org/publicpolicy/jan2015OHRPcomments/

IRBNet Forms & Checklists

The IRB Office will soon begin reviewing and updating the submission forms and checklists posted in IRBNet. To ensure you are using the most recent version, please use the documents posted in IRBNet when preparing a new submission. Changes to documents will also be announced in this newsletter.

To access submission forms and checklists in IRBNet, go to the right navigation bar, click on "Forms and Templates". Then click the dropdown menu on top of the page and choose the second option "CHW IRB Milwaukee, WI Documents for Researchers".

Questions, Comments, or Suggestions

Your thoughts and recommendations for future newsletter topics are much appreciated! Please send your ideas and feedback to Julia Kennedy at jkennedy@chw.org.