Children's Hospital of Wisconsin

Human Research Newsletter

JULY 31, 2019 VOLUME 5, NUMBER 3

INSIDE THIS ISSUE:

Reliance Process Update

In an effort to make the reliance process more efficient, consistent and to gather as much required information as possible UP FRONT, we have created an easy to use 'form' hyperlink button that generates an email template for new reliance requests on our HRPP website.

The email template includes a list of documents that are commonly required/preferred as well as fillable sections with examples. While utilizing this email template is not required at this time, it may be required in the future, so please consider trying it out!

As another way we are making the reliance request initiation process easier, we have also added links to the Investigator Reliance Request form on the website on the landing page and on the Forms page. The form on the website is the same as the form in IRBNet and will be kept current when/if that form is updated.

We have added sections of the Submission Checklist Guidance Document to include reliance project package types (sometimes referred to as 'Shadow Submissions'). At this time, these are required for any studies where other sites (besides the SEWIC sites) are involved and CHW IRB is not the Reviewing IRB. For those of you familiar with the 'Shadow Submission' process, the checklist should look pretty similar to what has been required in the past with one important update: the Registration Page will now be required for all Continuing Review packages (consistent with CHW IRB reviewed studies). This is to help ensure we have up to date information for studies that continue to enroll at CHW. We have published an updated Guidance – Document Submission Checklist in IRBNet and on the website.

Finally, we have a flow sheet to help visualize the reliance request initiation and CHW Institutional Local Context Review process. This simplified, high-level visual includes many of the basic steps that occur, but these steps may vary by request. Also, there may be other departments involved; however, we wanted to try to include what happens in the HRPP and with researchers mainly. This will evolve over time as our processes continue to improve. This flow sheet is available on the HRPP Guidance web page.

Many people are currently working together to continue to help develop/improve the reliance initiation process and ensure continued institutional oversight of studies ceded to other IRBs. There will continue to be updates and we will continue to inform researchers about these updates as they come up. We continue to welcome your suggestions and feedback.

As a reminder, even if another IRB has regulatory oversight of a study, CHW maintains institutional oversight of every study occurring within CHW space, with CHW subjects, or with CHW investigators. If you have any questions, please reach out to us at CHWIRBReliance@chw.org.

Use of Imaging in Research Studies

When a research study involves use of imaging tests (X-ray, MRI, CT, Ultrasound, PET/MRI) to be performed at CHW, there are steps that need to be taken before submitting the project to the IRB.

Safety Committee Review

If the imaging is being done solely for research purposes the research must first be reviewed by the appropriate safety committee. Research that involves the use of X-rays (including DEXA) or CT scan is reviewed by the CHW Radiation Safety Research Sub-committee and possibly Wisconsin's Department of Health and Human Services. Research involving MRI or PET/MRI is reviewed by the CHW MRI Safety Committee. See Guidance – CHW Research Project Review by Safety Committees. This safety committee approval must be included in the submission to the IRB.

Review by Imaging Department at CHW

Even if all the imaging being done as part of the research study is considered standard of care, if the imaging will be done at CHW/with CHW equipment as part of a research study (it is described in the protocol), the CHW imaging department needs to be notified/consulted prior to submitting the study to the IRB. Beyond any safety considerations, the imaging department needs to be able to plan for staffing, scheduling, use of the equipment and work out logistics in order to be able to support the study efficiently and without disruption to the department. A form is being developed by the imaging department which will need to be completed and provided to Linda Strain (Manager, Imaging) for review. This will be made available to the research community when it is finalized.

In the interim, the PI/research team should contact Linda Strain at 414-266-3171 or LStrain@CHW.org to notify her, discuss the upcoming research project, and answer any questions she may have.

As with the requirement for other departmental sign off – when the research study (or amendment adding imaging) is submitted to the IRB it should include either documentation from Linda that the imaging department is aware of and can support the study, or a sign-off of the package in IRBNet from Linda.

Use of MRI for Research in Non-Clinical Areas

When a research study proposes to utilize MRI on a pediatric population in non-clinical areas, or uses MRI equipment outside of CHW space (such as the GE MR750 3.0T scanner located in the Froedtert Pavilion for example) there are special considerations that the CHW IRB must take into account for the protection of these subjects. While the device and procedure itself may be considered minimal risk, the age of subject population and potentially their underlying health status, as well as the location of the MRI machine (in a non-clinical area) may increase this risk or warrant special consideration. The CHW IRB will review these studies carefully and certain parameters must be in place in order for the IRB to consider approving the MRI use in these cases.

The CHW IRB is working on a guidance for investigators regarding these considerations and the parameters under which the CHW IRB may approve these studies. In the meantime, the IRB will likely have additional questions and request more information from the investigator about these submissions. Feel free to request an IRB consultation to discuss these cases prior to submission.

CHW IRB Office Hours Update

In the last newsletter we announced the implementation of IRB Office hours as dedicated time we are available for researchers to come to the IRB office with questions, for a consultation, etc. This has been regularly utilized – and as such we will continue to offer this. If utilization demands, and our availability allows we may expand these hours if needed.

June 4, 2019	3 Participants
June 11, 2019	1 Participant
June 18, 2019	2 Participants
June 25, 2019	0 Participants
July 2, 2019	5 Participants
July 9, 2019	3 Participants
Total Since Beginning of June	**14 Participants**

Compliance Corner

Use of alteration of HIPAA authorization

Study teams sometimes ask for an alteration of HIPAA authorization in which the signature is waived. In these cases the PI needs to demonstrate (as indicated in the HIPAA regulations) that obtaining this is not feasible. If the research team is able to locate and contact the family by telephone, then it likely feasible to mail the HIPAA authorization for signature. When these situations arise, they will be assessed by Corporate Compliance on a case-by-case basis prior to the IRBs final determination.

Use of "cloud" based platforms to store research data

When an investigator proposes to use storage platforms that have not been previously vetted, many factors need to be considered in this assessment. If any major breaches occur, CHW as the covered entity has a great deal of accountability. As such, CHW Corporate Compliance needs to be the final judge of the appropriate data protections of any "cloud" storage platforms. When these situations arise, they will be assessed by Corporate Compliance separately.

As much as researchers would like CHW to have specific guidelines in place to cover these types of situations, Corporate Compliance feels it is better for these situations to be assessed individually, in the context of what is being done for the research, and in light of all the factors that may have an impact.

Community Rep Reflections

This is the first in a new regular feature of the Human Research Newsletter. Each issue, we will be publishing some reflections, observations, thoughts etc. from our community representatives on the committees. They offer a unique and valuable perspective in the review of research happening here at Children's.

Tyler Pease - Board 1

Reflections after joining:

I really enjoy the vast subject matter presented and the involvement in so many varied studies and disciplines. I do sometimes find it frustrating reading the consent forms. I am not a scientist or a person with a medical background. I am also a parent of a child that participated in a number of studies and I read these to provide legal consent. I would really like the researchers to focus on the required elements of the consent and information relevant to a decision on whether or not to participate. I would like to see consents condensed down to a length that is not so onerous to a parent under stress. The

consent forms I review as an IRB member are frequently 20-30 pages in length.

Stan Garbasz – Board 2

Upon reading a request to write an article for a new column called "Community Representative Reflections" I started to think about what perspective I could provide and whether an article about my role as a community member on Institutional Review Board #2 would sound like a plea for attention or an explanation about the work I do on the board. We'll see where it ends up at the end of the article.

I was made aware of a position on the board in August of 2014. I remember talking to my boss about the position and discussing how I was going to make it fit into my work schedule, I was a project engineer at the time and the meetings occurred during my normal working day. I've since retired so it's no longer an issue. We came up with an agreeable plan where he emphasized that my regular work would take priority over this new venture, but he gave me the flexibility to show up late for work and stay late to meet my time requirements. But he also shared with me that he too at one time had the opportunity to volunteer some of his time on a community-based board and chose to put it off to the future. As it turned out the opportunity for him did not arise again. Due to some changes in personnel within Children's Hospital of Wisconsin IRB it was January 2015 before I was able to attend my first meeting and was invited to be part of IRB #2 and was sent the schedule for the meetings for the rest of the year. True to form I sent back that a correction was needed to the schedule as one of the dates fell on a Friday and our meeting day was always the third Wednesday of the month. Looking back, I wonder if they felt pleased that I found this mistake or were regretting the offer to participate on the board. I feel honored that I was asked to be part of this group and unlike my boss I didn't want to risk passing it by and maybe never being given another chance to join.

It's interesting to be part of a group where you know that your qualifications are less than the other members yet the charter for the group dictates that someone like you be part of the group and even requires your attendance at the meetings in order to conduct business. Within the training that I had for this work I remember reading about other community members and that they too needed to address the question of what are the expectations of community members. After all no one expects community members to start taking premed classes to gain insight into the medical research field. However, with my background in engineering and a career that included meeting industry standards or corporate standards as well as writing various documents whether they be scopes of work, engineering standards or routine correspondence to other companies I felt that I could be a useful part of the board.

So now after over four years of time on IRB #2, and having done over 60 reviews maybe it is time to offer some insight as to why I bring up

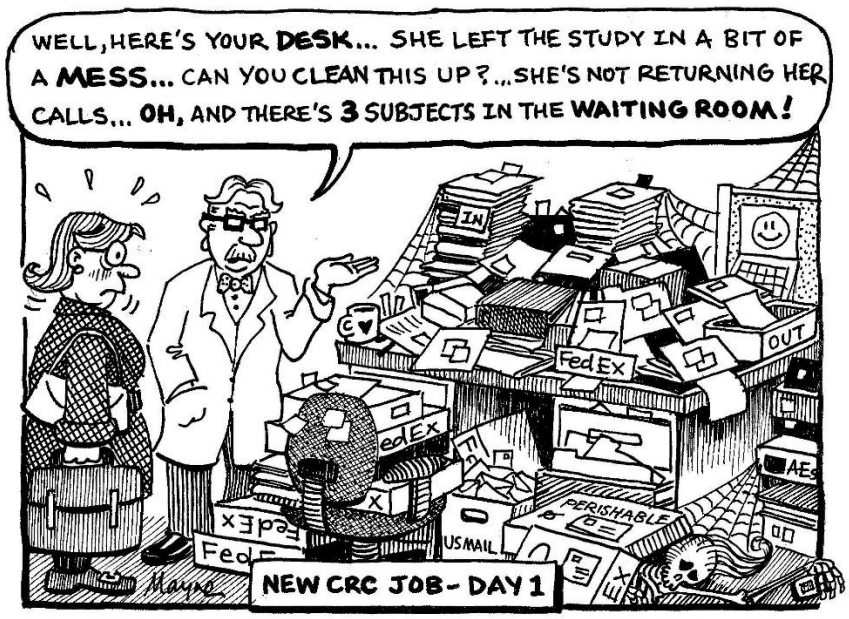
Did you know... in order to maintain hospital accreditation and compliance with the Joint Commission standards it is crucial that any skill performed on a Children's patient is only performed by Children's Hospital employees or providers who have competencies on file.

Who is considered a Children's Patient? A Children's patient is any person who is being seen for care at Children's hospital regardless if it is for clinical or research care.

What does this mean for my research? The Pediatric Translational Research Unit (TRU) is available to provide these patient care services or can direct you to appropriate personnel.

some of the things that I do. Even though I'm not a member of the research team whose work I review, I find it difficult to not suggest changes that I believe will make the various documents more professional. In my career I've read many people's works and I find that the less professional a document looks and reads the less confidence I, or possibly others, will have in what is written. And in the context of needing to get subjects to agree to having their children be part of a research study I don't want any study to miss out on signing on new subjects because the documents presented to them left them with doubts about what was going to be done, or the capabilities of the research team.

It's interesting sometimes what triggers memories of past events. Writing this article reminded me of the time in college where I had written a computer program which did not execute properly. Having searched for my mistake it finally came time to turn it in which I did knowing the work was not right. When I got my work back, I was pleased with the grade given that the program didn't work, but I had to find out what was wrong. This time I found my mistake the first time I went through the program. I had entered the number 8 where I should have entered the letter B in one line of the program. If only I had someone else to review my work maybe the mistake would have been found before I turned in the work and I'd have gotten a better grade. It's too late for that happen but in the meantime I'm happy to part of IRB #2 and review your research protocol.



Spotlight on the IRB Members

This is the first in another new regular item in which we will spotlight one of our IRB members so our research community can get to know them better!

First up – Community Member **Tyler Pease** – Board 1

Briefly describe your professional background & career
I have a BS in engineering from UW-Stout & an MBA from Marquette University. My career has been primarily as a Sales Engineer focused on protective packaging for sensitive electronics and medical equipment. During the last 30 years, I have designed and packaged everything from small electronic chips the size of a pencil eraser to 20,000# magnets that fly on airplanes.

Tell us what motivated you to become an IRB member
In December 2010 my daughter Sarah was diagnosed with AML; she passed away in July 2011 at age 16. Sarah was treated at CHW and I was really impressed with the people and the facility. I knew as we were still fighting and getting treatment at CHW that I eventually wanted to somehow be involved at CHW. It took me several years before I was emotionally ready to get engaged. I also realized that while I was ready to give back, I needed to do so in a method that did not involve working directly within the hospital as I found it too emotional. I also wanted to somehow be involved with new treatments and procedures that can bring hope. The IRB seemed to be the perfect solution to what I was looking for.

What is your favorite personal time activity?
My favorite personal time activities are quite unrelated. I love bike riding (road) in the summer; I love being out in the sun, heat and just going about 50 miles without being bothered! Every year I participate in the Leukemia & Lymphoma Society (LLS) Scenic Shore 150 as well as weekly fun rides around the city. My other passion is playing the piano- I'm not that good but I love it and find it relaxing. It's my Yang to the rest of life's Yin!

The HRPP v. the IRB

These terms sometimes get used interchangeably but there is in fact a difference.

An HRPP, or Human Research Protection Program, is a collaborative effort among those who develop, conduct, review, approve and facilitate research with human subjects. The goal is to protect research subjects through support, guidance, and education to facilitate

research that is ethical and scientifically sound. All of the components must work in tandem and balance to uphold human subject research protections. The HRPP includes many elements such as:

- The institution (Corporate Compliance, Risk Management, Legal, the Institutional Official, Grants and Contracts, etc.)
- The investigators and their research teams
- The Institutional Review Board (IRB)
- HRPP/IRB Office staff
- Regulations and Policy
- Sponsors/Monitors
- Human participants

The IRB, or Institutional Review Board, is one component of the broader HRPP. The IRB consists of those individuals who sit on each committee and review individual research protocols to make specific determinations based on specific regulatory criteria. One definition states an IRB is "any board, committee or group formally designated by an institution to review, approve the initiation of and to conduct periodic review of research involving human subjects." Its primary purpose of this review is to ensure the protection of the rights and welfare of human research subjects.

This committee, based on federal regulations (45 CFR 46.107 and 21 CFR 56.107), must be composed to include:

- A minimum of 5 members with at least one being unaffiliated with the institution
- A diverse group of individuals
- Customized to each institution/type of research reviewed
- One member must be a non-scientist
- Committee must have at least one physician (for review of drug/device studies)

Here at CHW we have two committees, all volunteers, made up of pediatric physicians from a variety of specialties, as well as others with special expertise such as:

- Biostatisticians
- Psychologist
- Pharmacist
- Nursing providers
- Clinical Research Manager/Coordinator
- Two community, non-scientists on board 1, one on board 2 (currently onboarding two additional community members, one being another non-scientist)

Our IRB analysts are also alternate members of these committees to allow them to be delegated certain reviews for which they can make final approval determinations.

All of our IRB member go through a robust onboarding and training process as well as continuing education.

Research Ambassadors' Angle

Earlier this year, the MCW Office of Research launched the Research Ambassadors program for the purposes of education, communications and networking. Ambassadors are voluntary staff and faculty members who function as champions of research procedures, resources and best practices within their department, division, center, or lab.

Ambassadors serving the Pediatric / CHW research community are:

Theresa Kump
Department of Pediatrics
tkump@mcw.edu
414-337-7144

Nicholas Peterson
Department of Surgery / Herma Heart Institute
npeterson@chw.org
414-266-1753

Ed Bedjeti
Urology: Pediatric Urology / Pediatric Surgery
ebedjeti@chw.org
414-337-3441

We will be posting updates from the Office of Research here in this newsletter and passing along new information as needed.

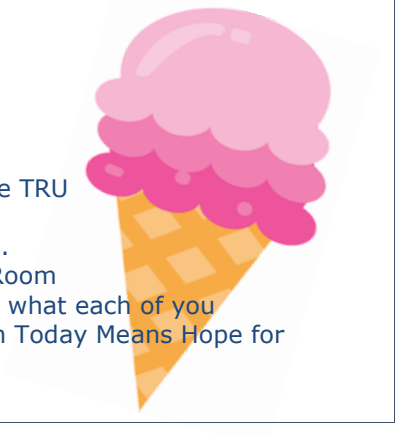
Please reach out to us if you need anything or have any suggestions for how we can best serve you!

For a listing of all Ambassadors and more information about the program:
https://infoscope.mcw.edu/research/Research-Ambassadors.htm

PEDIATRIC TRU UPDATES

EPIC Reminder: Jeff Crawford is your Research Epic Credential Trainer. If you ever have any research related questions, comments, or concerns please contact Jeff – jcrawford@chw.org or 414-266-7254

Save the Date!



On Behalf of CRI:

MCW Research Day Ice Cream Social in the TRU

When: Thursday, September 19 2-330pm.
Where: C4S – Pediatric TRU Conference Room
Why: Come to the TRU as a thank you for what each of you contributes to pediatric research! Research Today Means Hope for Tomorrow!

For more information and updates on education opportunities visit the HRPP webpages

Children's Hospital of Wisconsin Human Research Protection Program/Institutional Review Board

Children's Corporate Center
999 North 92nd Street, Suite #120
Milwaukee, Wisconsin 53226

We're on the Web!

https://connect.chw.org/hrpp

Questions, Comments or Suggestions:

Your thoughts and recommendations for future newsletter items are much appreciated. Please send ideas and feedback to Michelle Martin, CIP, CCRP at MMartin@chw.org

Education Opportunities

Small Group Education Sessions-TRU and IRB Staff

Join IRB and TRU staff for informal presentations and small group discussions of select research topics. Space is limited, however, the same topic will be discussed at the two sessions each month. This will also be an open discussion and a chance to bring your questions or get assistance with EPIC or IRBNet.

These will meet in the TRU: Center 4 South, Main Hospital

August 6th, 2019 @ 2:00pm, TOPIC TBD

August 22nd, 2019 @ 10:00am, "Children's Experience Promise" and TOPIC TBD

IRBNet Document Library and Website Updates

The IRB office is reviewing and updating forms and documents posted in IRBNet and on the HRPP webpages. To ensure you are using the most recent version, please use the documents posted in IRBNet when preparing a new submission.

Forms/guidance/Web pages recently posted:

- **New** Guidance added to IRBNet and Website: Reliance Agreement Internal Process Flow Sheet
- **New** Guidance added to IRBNet and the Website: CHW Research Project Review by Safety Committees
- **New** Guidance added to IRBNet and the Website: Recruitment for Human Subject Research
- **Updated** Guidance: Document Submission Checklist
- **New** Form added to website: CHW Reliance Request Form