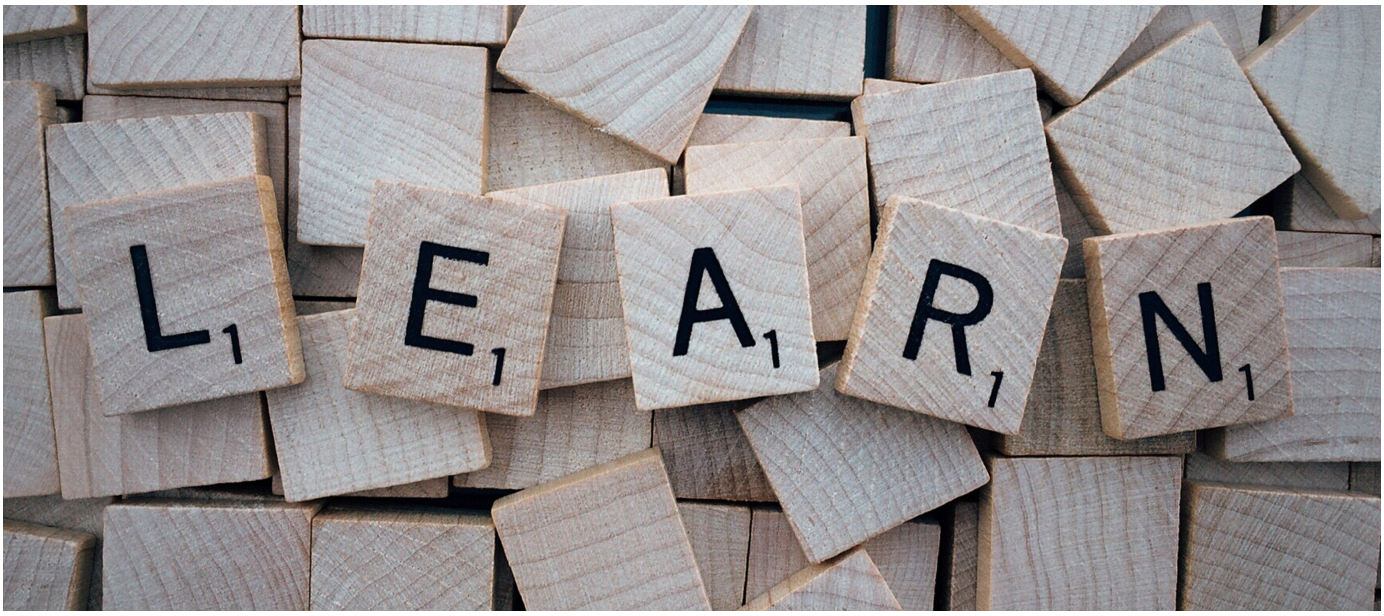
JULY 2020 | VOLUME 6 | ISSUE 2

HUMAN RESEARCH NEWSLETTER

A QUARTERLY NEWSLETTER FROM
THE CHILDREN'S WISCONSIN HRPP/IRB



WORKING FROM HOME & THE RETURN OF OFFICE HOURS

A MESSAGE FROM THE HRPP OFFICE

Remember when working from home felt like a fantasy from Neverland?

We don't need Peter Pan to take us there – we're already here. Soon after COVID-19 impacted the Greater Milwaukee Area, Children's Wisconsin was quick to allow those who could work remote, just that opportunity.

The Children's HRPP has been settling in to this new environment ever since. Already having two remote IRB Analysts, our transition was, perhaps, a little more natural than other departments. IRB Meetings have also moved to being held entirely remote, and have been very efficient in this environment. We're grateful Children's provides innovative technology that allows us to communicate effectively, even while working remote.

IN THIS ISSUE:

During these unprecedented times, we understand the need for quality education remains. We've received overwhelming support for our Open Office Hours, and we're happy to announce Open Office Hours will be returning for study teams! Open Office Hours will be offered Tuesday mornings from 9:30 – 11:00 AM. An e-blast will be sent with more information soon.

We hope everyone has been able to settle in to their "new" normal. Remember, you can always reach us at our general inbox if you have any questions or want to share successes.

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

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

For more information on our education opportunities, visit our NEW Educational Offerings Connect Page!

RESEARCH BILLING UPDATE

NEW CONTACT

Candi Hust is the newest member of the research billing team and will begin to assist with processing charge sheets, sending invoices, emailing for status on unpaid invoices, etc.. Please ensure that Candi and her supervisor, Judy Pokos, are copied on all charge notification form correspondence moving forward. An updated charge notification form including Candi and Judy's information will be shared with the research community shortly. Candi and Judy's contact information has been included below.

Candi Hust
Phone: (414) 266-6255
Email: chust@chw.org

Judy Pokos
Phone: (414) 266-3164
Email: jpokos@chw.org

IMPORTANT REMINDERS

TIPS FOR SUCCESS

Did you know...?

In order to maintain hospital accreditation and compliance with The Joint Commission, it is crucial that *any* skill performed on a Children's patient is *only* performed by Children's Wisconsin employees or providers who have competencies on file.

Reminder #1
As research ramps up and COVID-19 restrictions are gradually lifted, please remember to follow our guidance on the HRPP Connect Page and to follow the process of contacting the pTRU for approval if you would like to resume face to face interactions in your research.

Once the pTRU gives the green light, double check your protocol to determine if the research will be resuming as already approved by the IRB, or if there are modifications planned to mitigate COVID risk that will need an amendment submitted for IRB review and approval. We will be updating our guidance with instructions if your study involves face-to-face contact and all research interventions take place outside of Children's Wisconsin facilities. Please watch for the revised guidance.

Reminder #2
If changes are needed to the Children's informed consent template documents, either because a sponsor is requesting this or the PI is requesting, there is a request process that should be followed before submitting the package for review. The Template Change Request Form can be found in IRBNet and includes instructions. Essentially, this form must be completed to obtain approval to submit revised language, and should indicate what needs to be changed along with the rationale for any changes. This should be sent to the main IRB email at

The request will be reviewed and the decision documented on the form. The form will then be returned along with any sections that need updating on the unlocked template. If the request is approved, this form should be included with the package submitted so the analysts know that any changes to the template language have been reviewed and are acceptable.

Reminder #3
When study teams are asked to submit an amendment to add Waivers of HIPAA and Consent to cover the use of PHI once subjects reach age 18, the protocol summary must also be updated to indicate the process now in place for those reaching age of majority.

> *Make a habit of two things — to help, or at least, to do no harm.*
>
> *Hippocrates*

STAFFING UPDATE

NEW BEGINNINGS

In case you were not aware, at the end of May Sue Ahlf, IRB Analyst, took a new position. We lost a friend at Children's Wisconsin but gained a friend at the Milwaukee VA. Sue is very much missed! The good news is that our efforts to recruit and fill that role have been rewarded with applications from several qualified candidates. It was a difficult decision, but we have selected a candidate who has accepted our offer. We look forward to introducing our new IRB Analyst in the next issue.

INTRODUCTION TO THE CHILDREN'S IRB

HELD MONTHLY VIA ZOOM | 8:00AM - 12:00PM | 2020 EVENT SCHEDULE

The Children's Wisconsin IRB is offering a new, regular session focused exclusively on introducing staff new to working in pediatric research to the Children's Human Research Protection Program (HRPP)/IRB submission and review process. These sessions will provide practical advice for working with the Children's HRPP Office and help ensure successful IRB submissions and ongoing (regulatory) study management.

This is intended for those who will be working regularly with and submitting to the Children's IRB.

Registration
Visit our NEW **Educational Offerings Connect Page** to register and for more information. Remaining 2020 sessions will be held remotely via Zoom.

**A particular monthly session may be postponed if there are less than 5 attendees.*

RELIANCE UPDATES

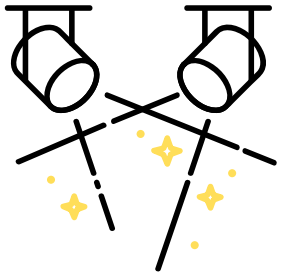
PROCESS UPDATES

As part of our commitment to continuous quality improvement, we are excited to announce that we have made updates to our reliance request process, which we anticipate will help decrease our turnaround times on initial shadow submissions and ensure consistency between projects.

We have modified an existing worksheet to be used by researchers. For those researchers familiar with the pediatric NCI CIRB process, this worksheet will simply be an updated version of that. For those researchers who do not currently utilize a worksheet, this will be new, but its intent is to help guide researchers on what needs to be submitted within the initial shadow submission in IRBNet. This document has questions and check off sections geared towards ensuring all necessary documents are in the submission and that sign offs are complete.

We have a corresponding worksheet for our staff to help us be consistent and efficient as well. In addition to the worksheets, we wanted to let you know that all members of our team are training to review shadow submissions. These improvements will result in a smoother, quicker process for all. Worksheets can be found in IRBNet and on the HRPP Connect site.

MEET YOUR BOARD MEMBERS



FEATURED IRB MEMBER

Cassandra Baumgart, MS, MLS (ASCP), CIP
(AKA Cassie, or 'Eagle Eye')

Briefly describe your professional background and career:
I started my professional career by earning two Bachelor's degrees in Medical Laboratory Science (MLS) and Biochemistry. I was an undergraduate researcher in Organic Chemistry and finished up my clinical practicum in MLS at the Mayo Clinic in Rochester, MN. I became a Certified Medical Laboratory Scientist and worked in a clinical lab in Green Bay for 2.5 years. I proceeded to clinical research after that and I worked directly with pediatric oncology and gynecology/oncology subjects as a Clinical Research Associate. I also prepared submissions to the local IRB and CIRB. I obtained my CCRP shortly before I came to Children's Wisconsin. In November of 2016 I started my journey here as an IRB Analyst and became a Certified IRB Professional when I was eligible. I have recently been promoted to Senior IRB Analyst. I also spend about half of my work time on reliances.

Tell us what motivated you to become an IRB Member and Analyst:
I love science and research, but working directly with subjects was too hard on my psyche (I was unable to emotionally distance from my subjects). I wanted to be able to continue to help research subjects and help further science but needed some physical and mental distance. Helping ensure the safety of research subjects 'in the background' fit well with my mental and professional goals.

I knew a little of IRB work and had experience as a researcher, but if I'm honest, did not recognize the breadth of knowledge and skill it takes to be an effective analyst or member before starting! It turned out I'm not too shabby at this work AND I really like it!

If time and money weren't a consideration, what would you do differently?

I would travel WAY more if I wasn't stuck paying off these dang student loans and could save up some PPL! I have traveled to some spectacular places with my husband and would love to take my kids to more places. Ireland, Germany, Poland, Costa Rica, and MANY more US places are on my list of hopeful destinations.

We're on the web!
https://connect.chw.org/hrpp

Reliance Questions? You can initiate the Reliance Request Process by visiting *our HRPP Connect Page*. Look under, "Reliance requests," on our homepage. You can find insight to the reliance process by viewing our flow sheet.

Questions, comments, or suggestions: Your thoughts and recommendations for future newsletter items are much appreciated. Please send your ideas and feedback to Michelle Martin, JC, CCRP, CIP at mmartin@chw.org.

PEDIATRIC TRU

UPDATES AND REMINDERS

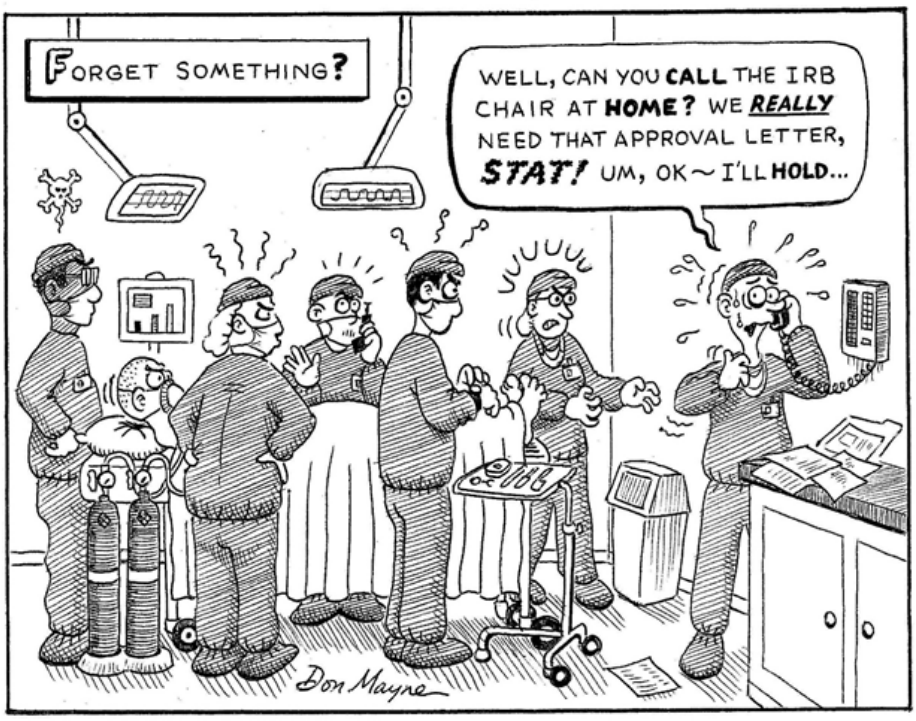
Current pTRU Hours:

Monday:	7:30 AM - 5:00 PM
Tuesday:	7:30 AM - 6:00 PM
Wednesday:	7:30 AM - 5:00 PM
Friday:	7:30 AM - 4:00 PM

At this time, we are unsure as to when we will reopen M-F. We will reassess in early September but the soonest we envision being open M-F is October 2020.

Reactivation of Research

Studies designated as Phase A or B are approved to resume on campus. It is unclear when Children's will move to Phase C of Research Reactivation. If you have questions about when you can resume specific research studies or to seek approval for a study monitor visit, please contact Cristen Hemstead (chemstead@chw.org) and/or Beth Gissibl (bgissibl@chw.org). Please include justification/rationale as to why a monitor visit cannot take place virtually.



Join us for Open Office Hours! Open Office Hours are returning every Tue from 9:30 - 11:00 am via Zoom! Stay tuned for an e-blast with more information coming soon.

Open Office Hours is a chance for study teams to drop-in for general questions and guidance, typically lasting no more than 15 minutes.

Have complex questions? Consultations are available to study teams with complex questions that may take significant time to answer. To schedule a consultation, please complete our Consultation Request form on our *HRPP Connect Page*.

BACK TO BASICS

WHAT DO I SUBMIT TO THE IRB AT THE TIME OF CONTINUING REVIEW?

The IRB has a regulatory responsibility to conduct continuing review of the current status of an ongoing research project (45 CFR 46.103(b)(4). Per OHRP guidance, this must be a "substantive and meaningful" review. Specifically, HHS and FDA set forth the regulatory criteria that must be satisfied in order for the IRB to approve research (".111" criteria). These criteria broadly include determinations by the IRB regarding the risks and potential benefits, appropriateness of informed consent process, and any additional safeguards for human subjects that may be vulnerable.

The IRB must determine that these criteria are satisfied both at the time of initial and continuing review. At the time of initial approval, the IRB review is based on projected information. Once the study has started, information is collected that may have been previously unknown. When conducting continuing review, it is important for the IRB to understand whether any new information is available – either from the investigators or from other sources – that could alter the IRB's previous determinations, particularly with respect to the risks and possible benefits to subjects.

Of note, information regarding any unanticipated problems involving risks to subjects or others (hereinafter referred to as unanticipated problems) that have occurred since the previous IRB review in most cases will be pertinent to the IRB's determinations at the time of continuing review.

In order to conduct this review, the Continuing Review submission package ("CR") must include all documents that are still relevant to the conduct of the study, even those that had been previously submitted with the initial submission or any subsequent amendments. There is a checklist available in IRBNet and on our HRPP web pages under Guidance to assist with determining what is still relevant. This checklist is all-inclusive and lists the documents that potentially need to be submitted. However, you will need to consider whether each document is relevant for a particular study depending on the type of study and the current stage of the study.

For example, if the study is closed to accrual, and there is no need to consent minors when they reach the age of 18 due to the nature of the study (such as when the subject's participation will be complete before reaching the age of majority) – then the consent documents would no longer be relevant to the conduct of the study at the time of CR and would not need to be included in the package.

***To register for education sessions*, visit our NEW** Educational Offerings Connect Page**.** Space is limited. For more information, visit us on Connect.

To ensure you're using the most current documents, always access our forms, templates, and documents directly from IRBNet.

In another example, although the study may no longer be enrolling, from a HIPAA perspective, and if identifiable information is still being used/analyzed, then HIPAA waivers need to be in place to protect the PHI to be HIPAA complaint. So if identifiable data is still being used/analyzed or medical records are still being accessed, then any previously submitted HIPAA waivers would still be relevant and should be submitted at the time of CR.

If there are patient facing materials such as advertisements, patient brochures, etc. that are no longer being used for recruitment, then these would not have to be included in the CR package.

The exact documents needed will depend entirely on the specifics of each study and it is up to the PI to assess whether any of the study-related documents are still relevant, and then provide them in the CR package. If you have questions, please send an email to the main IRB office email address.

It is also important that the most current, clean version of the documents are submitted at the time of CR so the IRB is reviewing the most current versions and there is no question about whether changes are being made at the time of CR. Additionally, this is so you can be provided with stamped versions as appropriate. None of the documents should contain any change tracking, and they should be the version that was last approved by the IRB. It is the PIs responsibility to keep track of what approved document versions are the most current.

U.S. NEWS RANKS CHILDREN'S AMONG THE BEST

CHILDREN'S WISCONSIN RANKED IN SIX SPECIALTY AREAS

U.S. News & World Report has released their 2020-21 Best Children's Hospitals List and Children's Wisconsin was ranked in six specialty areas. These include:

- Cancer
- Cardiology & Heart Surgery
- Gastroenterology & GI Surgery
- Neurology & Neurosurgery
- Orthopedics
- Pulmonology

Over the past two months, it has never been more apparent that our staff and providers are Children's greatest asset. While navigating the COVID-19 pandemic since March, we have still been able to provide exceptional care for our kids.

Honors like this wouldn't be possible without our incredible team of providers and staff who work together every day to ensure the kids we serve receive the best and safest care. The rankings are a clear indication of our values of Purpose and Innovation and a commitment to our vision that Wisconsin kids will be the healthiest in the nation.

SMALL GROUP

Q3 AND Q4 DATES VIA ZOOM

Join the Children's HRPP/IRB Office and the Pediatric Translational Research Unit (pTRU) Staff for Small Group to discuss select research topics. The same topic will be discussed at both sessions each month. An open forum, you'll have the chance to get your own questions answered, and get help with Epic or IRBNet.

Small Group is being held via Zoom.

Remaining 2020 Schedule:

Aug 05, 2020 @ 11:00am
Aug 17, 2020 @ 2:00pm

Sep 02, 2020 @ 11:00am
Sep 21, 2020 @ 2:00pm

Oct 01, 2020 @ 11:00am
Oct 20, 2020 @ 2:00pm

Nov 05, 2020 @ 11:00am
Nov 17, 2020 @ 2:00pm

Dec 03, 2020 @ 11:00am
Dec 15, 2020 @ 2:00pm

ADMINISTRATIVE UPDATES

UPDATED RESOURCES

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

Recently updated policies, guidance, and forms:

- Assent Policy
- Exempt Policy
- Continuing Review Policy
- Expedited Review Policy
- International Research Policy
- IRB Member Voting Policy
- Project Deferred to NCI CIRB Policy
- Federal Reporting Policy
- IRB Membership Policy
- CAPA Guidance
- Continuing Review Form
- Reliance Researcher Worksheet

Children's Wisconsin
Human Research Protection Program/Institutional Review Board
Children's Corporate Center
999 North 92nd Street, Suite #120
Milwaukee, WI 53226

Children's Wisconsin
Kids deserve the best.