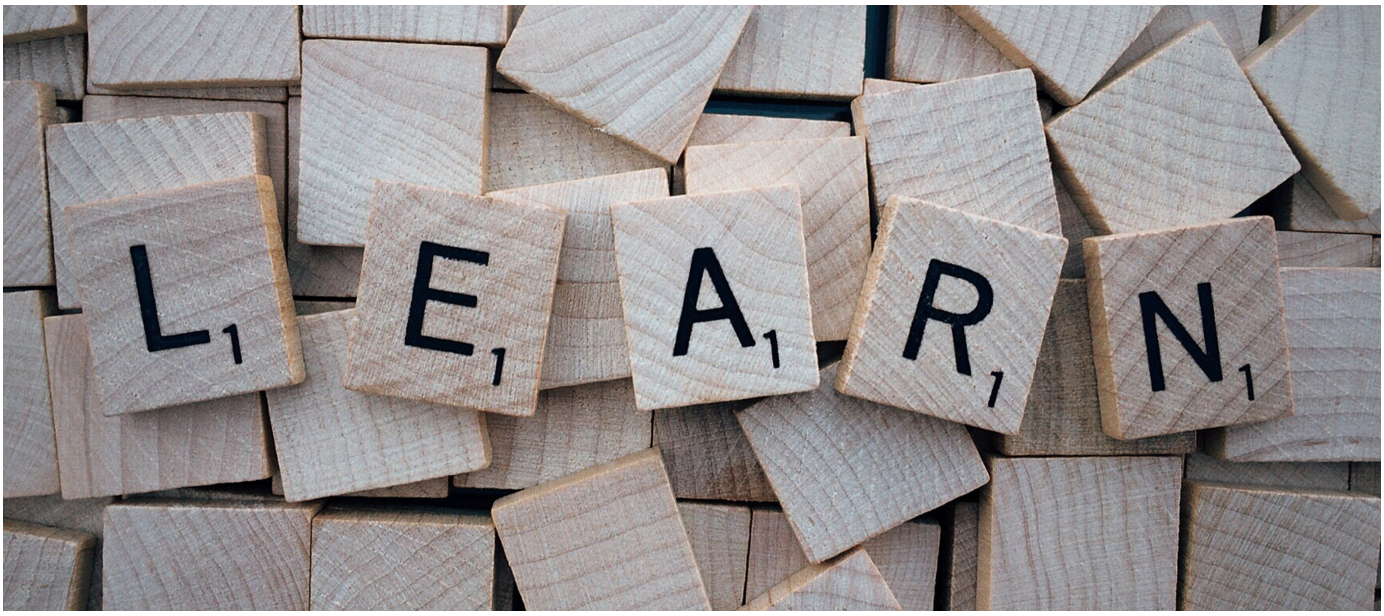
JANUARY 2020 | VOLUME 6 | ISSUE 1

HUMAN RESEARCH NEWSLETTER

THE CHILDREN'S WISCONSIN
HRPP/IRB QUARTERLY NEWSLETTER



NEW PROJECT APPLICATION

STATUS UPDATE

We have been actively working on a completely new application for human subject research projects submitted to the CW IRB and wanted to provide an update on it's status.

- This application will be an electronic form that will be completed in IRBNet, similar to the current registration page. This will include branching logic that will display different sets of questions dependent on answers to other questions.

- This new application will replace the need to upload the current summary form.

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NEWS, UPDATES, EVENTS

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- If the project is an investigator initiated study, there will need to be a formal protocol included in the submission along with the application. The IRB Office will provide resources for protocol templates.

- This new application is designed to capture the information and details needed for IRB Reviewers to determine whether the regulatory criteria for approval are met. The questions are similar to many such applications and have been vetted carefully by the CW HRPP, CW Leadership and in consultation with industry professionals.

- This new application is planned to be launched later this year. The exact date will be determined pending the build, testing, revisions (if needed), and education on the new form. We will announce a "go live" date when this is known, building in time for researchers to test it out in a training environment before it will be required.

- Once this goes live, it will be the application form for all new human subject research projects from that date going forward. As we continue to make process changes, it will also be required to update older projects – details on this will be forthcoming.

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.

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 and updates on education opportunities, visit the HRPP Connect Page.

UPDATED PROTOCOL SUMMARY FORM

AN INTERIM STEP TO OUR NEW STUDY APPLICATION

We are publishing an updated protocol summary form as in interim step to our new study application wizard in IRBNet. Because the IRBNet wizard application will not be available for a while, this interim form will help to capture more of the information the IRB needs to make the regulatory criteria for approval determinations, and should enhance the pre-review and approval process.

It is available for immediate use for all new study submissions. We will require the form be used as of Monday, February 17th. After that date, any new study submissions using the old form will be unlocked as an incomplete submission and you will be asked to complete the new form.

For retrospective chart review studies, please continue to use the Chart/Data Review Form in IRBNet. It may be updated in the future.

If you have questions, please plan to attend the small group sessions on February 6th and 18th where HRPP staff will be available to answer any questions you may have.

INTRODUCTION TO THE CHILDREN'S IRB

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

The CW IRB is offering a new, regular session focused exclusively on introducing staff new to working in pediatric research to the CW Human Research Protection Program (HRPP)/IRB submission and review process. This session will provide practical advice for working with the CW HRPP Office to 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 CW IRB.

This program will provide research staff with information on the workings of the CW IRB, while sharing tips and tools for submissions. It will also provide a basic introduction to concepts unique to research with pediatric populations that researchers need to be aware of (this is intended to be very introductory information and an overview, rather than advanced or in-depth coverage of these concepts.)

There is no cost to attend; prior registration is required; space is limited.*

Goals

1. Explore policies and operations of the CW HRPP/IRB
2. Introduce concepts unique to pediatric research
3. Learn best practices directly from HRPP/IRB Staff
4. Learn where to locate resources and how to get help from the IRB office when needed
5. Overview of the entire CW IRB life cycle of research projects
6. Briefly introduce CWs local review process for reliances
7. IRBNet overview and how-to tips

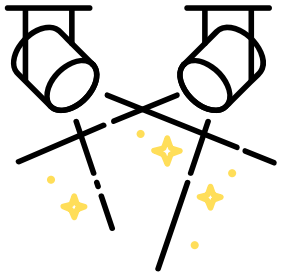
Registration

To register, please contact Brandon Woodruff by emailing BWoodruff@chw.org or by phone at (414) 337-7133. Include the session date, your name, phone number, and email address. If you're registering for a group, include these details for each attendee. View the 2020 Event Schedule above for meeting locations.

**A particular monthly session may be cancelled if there are less than 5 signed up to attend.*

> *There is no learning without remembering.*
>
> *- Socrates*

MEET YOUR BOARD MEMBERS



CO-CHAIR OF BOARD 2

Nathan Thompson MD, PharmD.

Briefly describe your professional background and career:
I originally went to pharmacy school at Butler University in Indianapolis. I was a practicing pharmacist for 5 years including my time in medical school. I attended medical school at Indiana University. I then moved to Milwaukee and have done all my post-graduate training at CW. I have been working in the PICU as a faculty member here for the past 6 ½ years with the last 5 being in the cardiac ICU.

Tell us what motivated you to become an IRB Member:
Due to my background in pharmacy, I have been interested in pharmacology and pharmacokinetics research in children. I was starting to do more clinical trials and thus working with the IRB more. When the IRB needed a new member to represent critical care, I was happy to join.

What is the most interesting place you have traveled and why?
My wife and I went to France last year for our honeymoon during the Yellow Vest riots. We got stuck in a protest one night in Avignon and got to experience tear gas for the first time. The event made for some really unique photos from our honeymoon.

ONE FORM, MULTI-FUNCTIONS

FORM UPDATE

You may recall that the revised 2018 Common Rule requirements at Section 46.109(f)(1)(i) eliminate the continuing review requirement for research eligible for expedited review unless an IRB determines otherwise. As a reminder, CW HRPP is currently applying the revised Common Rule on a per-protocol basis only when required by funding source, contract or other agreement.

For those minimal risk studies that have been approved under the revised Common Rule requirements, CW policies require that an annual status report be submitted when continuing review is not required. There are several studies approved last year which are coming due for a status report.

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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, CIP, CCRP at MMartin@chw.org.

SPOTLIGHT ON METRICS

AVERAGE TURN AROUND TIME:

8 Days

STAFF CHANGES

Instructions have been provided in the IRB approval letter and reminders are being sent through the electronic system. We have published the revised Continuing Review/Status/Final Closure Report Form in IRBNet.

To make it easier on our researchers, the document has been updated to reflect requirements for continuing review or status report so the same form can be used for all studies under CW IRB oversight.

You may notice that the form is not much different than our current continuing review application. This was an intentional decision made in collaboration with HRPP and Corporate Compliance Leadership. Our primary charge is the protection of kids, considered a vulnerable population, and we feel that the important information provided annually helps us safeguard the conduct of research.

It also helps us identify studies that may need assistance from our HRPP staff to ensure our standards for responsible study conduct are being met. We frequently identify opportunities for improvement via this review process and can reach out to our investigators and offer assistance when needed.

Join us for newly expanded Open Office Hours! Our Open Office Hours have been so successful, we have expanded them to every Tue 9:30 - 11:30am and every Fri 1:30 - 3:30pm.

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*.

We will periodically review our practices and reassess the appropriateness of this approach. This process may change in the future, and we will share updates as changes occur. Status reports will be reviewed by CW HRPP staff rather than by IRB chairs. This process is briefly outlined in our policy addendum, and will be described in detail once CW HRPP policies are updated.

COLLABORATION STATION

REMINDERS FOR SUCCESS

Before beginning the journey of collaboration with researchers or experts from other organizations, be sure to consider what may need to be on board from a regulatory and CW institutional standpoint. The CW HRPP has been working hard to ensure that anyone who is added to a project from an outside organization has the proper documentation in place. The requirements for the submission vary by what exactly each collaborator will be doing, whether or not they are engaged in human subjects research per our interpretation of *OHRP guidance*, and if engaged, whether there is an existing reliance agreement in place or whether their institution's IRB will be reviewing their activities instead.

The best way for the CW HRPP staff to know what documents need updating is for study teams to be very specific on the Amendment form. Include as much of the following as possible:

- Who will be working on the project and what institution they work for
- What data/specimens will be shared, why, and how the sharing will occur
- If the data/specimens they will be working with will be identifiable, coded (if so what type of code), redacted, or truly *de-identified*/anonymous
- Whether the other institution has determined the individual to be engaged (or not) and whether there is any IRB/HRPP determinations available

What is ALWAYS expected if someone from outside of CW/MCW will be involved and they ARE engaged:

- Documentation that a reliance agreement is in place OR the other institution's IRB approval needs to be present
- If no reliance agreement is in place and one is desired, we will request your team initiates by going to our *HRPP Connect Page*

Here are some documents that may need to be updated based on various scenarios:

	Collaborator on Reg Page?	Collaborator's role explained in detail in the protocol summary/app?	Waiver of HIPAA Authorization Updated?	Consent/assent/ HIPAA Authorization Updated?
Collaborator Engaged at CW and Other IRB Reviews NO Reliance Needed	No	Yes	Yes	Yes
Collaborator Engaged at CW and Other IRB does NOT Review Reliance Needed	Yes	Yes	Yes	Yes
Collaborator NOT Engaged at CW, per CW Likely no reliance needed, unless other institution requires it	No	Yes	Typically no	Not required, though may be helpful to explain if samples are coded/redacted rather than anonymous

This table is a **basic** guide and may vary depending on the exact collaboration, project and input from Research Compliance. As always, please refer to our Submission Documents Checklist for submissions.

PEDIATRIC TRU

PRICING CHANGES, NETWORKING, AND MORE

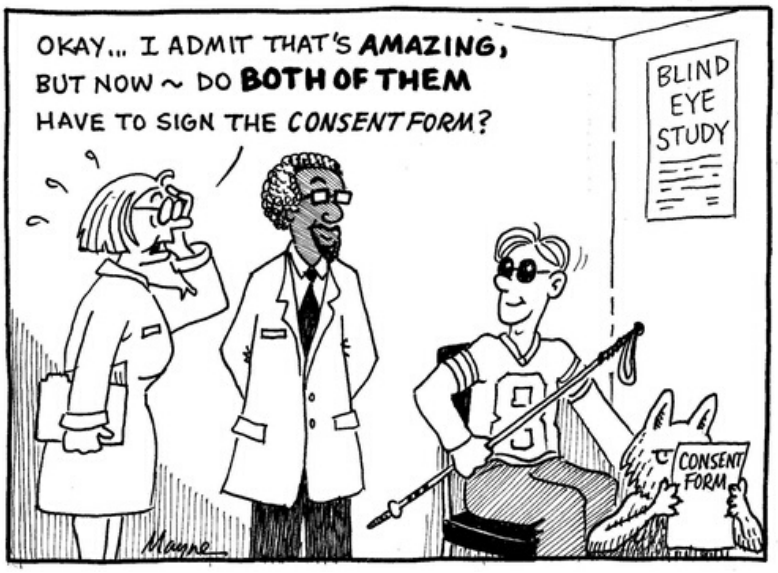
1. **Pediatric TRU prices will be going up effective 7/1/20**. Please refer to the "Memo on 2020 pTRU Pricing" that has gone out to study teams the week of Jan 13. If you missed this memo, please contact Beth Gissibl, pTRU Manager for more information.

2. **Join the pTRU Team at Firefly** on Wednesday, February 5th from 5:00pm - 7:00pm for an offsite post-holiday networking session. We hope you can make it!

3. **Save the Date**: February 25 from 9:00am - 10:15am for a large group education session in CW Auditorium. Topic: HIM labeling/scanning best practices and EPIC Tips & Tricks for Research.

4. With many new research support staff joining the CW/MCW family, please contact Beth Gissibl (BGissibl@chw.org) if they have yet to **attend a Children's Wisconsin Experience Promise Session**. This is a great opportunity to develop a more comprehensive understanding of what "our experience promise" is and the commitment we need from everyone who interfaces with our patients. This course takes an hour or less of your time.

5. **The pTRU is hiring** for 0.5 Clinic/Lab Assistant and 0.5 RN positions. Two of our staff have moved on in their careers due to obtaining higher level educational degrees. We are sad to see them move on but are excited for them and their futures! More to come as we fill our positions.



To register for education sessions, **contact Brandon Woodruff** by emailing BWoodruff@chw.org or by phone at (414) 337-7133. Space is limited. For dates and locations, visit *our Education and Training Page* on Connect.

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

2020 CLINICAL RESEARCH QUARTERLY ED

SCHEDULE ANNOUNCED

We're excited to announce the 2020 quarterly Clinical Research Education schedule!

- **February 25, 2020 @ 9:00am**
  - HIM Labeling/Scanning Best Practices and EPIC Trips & Tricks for Research
- **April 07, 2020 @ 9:00am**
  - Cell/Gene Therapy Start-up Processes, Considerations, and Lessons Learned
- **June 23, 2020 @ 9:00am**
  - Update from Children's Wisconsin IRB and Compliance
- **November 09, 2020 @ 9:00am**
  - Standardized Research Onboarding Process

All sessions will take place in the Children's Wisconsin Auditorium. A link to live stream will also be available via email in the days leading up to each session. Contact Jeff Crawford via phone or email if you have any questions relative to session content.

Jeff Crawford
Pediatric TRU Research Operations Specialist
JCrawford@chw.org
(414) 266-7254

RESEARCH AMBASSADORS

MONITOR ACCESS TO EPIC FORMS AND EPICCARE LINK

Research Monitor Access to EPIC Forms
Please submit Research Monitor Access to EPIC forms to:

Machelle Shulski (MShulski@chw.org); and,
Stephanie Ochoa (SOchoa@chw.org)

As a reminder, new monitors must review and sign the CHHS Confidentiality Statement of Understanding before obtaining their initial access to EPIC. After the research team submits the New Research Monitor Access to EPIC form, the monitor will receive their username and password directly from HIM.

Their login credentials will be used for all future monitoring visits, so please remind them that they will need to keep track of this. Subsequent monitoring visits can be arranged by submitting the Recurring Research Monitor Access to EPIC form.

EpicCare Link Access
The link to access EpicCare Link has changed.

The new link for monitor access is *https://epiccarelink.chw.org/*.

If you have technical issues on the day of a monitoring visit, contact Physician Support at 266-3499.

AMBASSADORS SERVING THE LOCAL PEDIATRIC RESEARCH COMMUNITY:

Theresa Kump
Department of Pediatrics
TKump@mcw.edu
(414) 337-7144

Ed Bedjeti
Pediatric Urology/Pediatric Surgery
EBedjeti@chw.org
(414) 337-3441

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

AGE OF MAJORITY

REFRESHER

The CW IRB/HRPP Office has been getting a lot of questions about what to do when subjects reach the age of majority (AOM), which in Wisconsin, is 18 years. When study procedures or interactions are ongoing (such as treatment, physicals, etc.) or while identifiable (or coded) data/samples are being accessed or used by the study team, any individuals who are enrolled as children with parental or guardian permission MUST provide their own consent and HIPAA authorization when they become adults. [If all links between any coded samples or data are completely destroyed—they are no longer identifiable].

As described in our guidance – Consent for Continued Participation When a Child Reaches Age 18 (found in IRBNet Forms and Templates) the permission and authorization previously granted by the parent or legal guardian is no longer legally valid. There is only one situation where re-consent is not required: if the CW IRB and Privacy Board determines that a waiver of informed consent and HIPAA authorization are appropriate per regulations and can be granted.

How can consent be obtained?

If the study procedures or interactions are ongoing, the current IRB approved consent and HIPAA authorization MUST be used. If the study procedures or interactions are completed, the current IRB approved consent and HIPAA authorization can be used, or if there is a currently approved consent for continued participation, this can be used instead. There is a template provided with the guidance - Consent for Continued Participation When a Child Reaches Age 18.

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If previously described in the submission and approved by the CW IRB, consent and HIPAA authorization can be obtained via phone AND mail.

If impracticable (e.g., unable to reach subject, large time between enrollment and AOM), to obtain consent and HIPAA authorization, a waiver of informed consent and HIPAA authorization may be appropriate and your team can request this in an amendment package.

What about biobanks or data registries?

These are the same as above — if identifiable (or coded) samples/data are being utilized, both consent and HIPAA authorization must be obtained OR a waiver of informed consent and HIPAA authorization must be in place. As always, if any of this is not clear, please reach out to our general line for help 414-337-7133.

WHAT WE LOOK FOR AT CONTINUING REVIEW

TIPS FOR SUCCESS

A comprehensive list can be found on our Submission Documents Checklist, but this is a quick reference table by study status/subject status of the more common materials.

Study Status					
Subject Status	Protocol summary or application AND Sponsor protocol*	Registration page and Continuing Review/Study Status Report form	Any local and Sponsor* Consent materials (parental permission, consents, assents, HIPAA) documents	Any HIPAA or Consent Waivers	Recruitment, patient, or data collection materials (ads, flyers, questionnaires, surveys, data collection sheet)
Open to Enrollment (or data collection ongoing)	All documents are required				
Closed to Enrollment (some subjects still on regimen)	Yes	Yes	It's a good idea, in case re-consenting is required	Yes	Recruitment materials may not be needed, but any patient documents or data collection documents should still be submitted
Closed to Enrollment – long term follow up of subjects	Yes	Yes	It's a good idea, in case re-consenting is required	Yes	Recruitment materials- No Patient documents or data collection materials – only what's needed now
Closed to Enrollment (or Data Collection is Complete) – analysis of identifiable or coded data	Yes	Yes	Age of majority consent and HIPAA Authorization if no waivers are in place	Yes	Likely no
Closed to Enrollment – all data has been stripped of identifiable information	Submit a closure rather than a continuing review/status report				

*If applicable to the study

COMPLIANCE CORNER

RECENT CHANGES IN EPIC

Researchers with Hyperspace and EpicCare Link accounts now have view-only access to Care Everywhere information that was retrieved into the CHW record while clinicians were providing/coordinating care. (Researchers will NOT be able to request updates or query new sites.)

For patients that have existing Care Everywhere links to outside records:

1. The Care Everywhere activity will automatically open and appear next to the Chart Review activity
2. Outside encounters will appear in the Chart Review>Encounters Tab
3. Outside labs will (again) appear in the Chart Review>Labs Tab (the outside labs will have an encounter type of "Reconciled Outside Data")

<u>When the next release of Epic software is installed on February 8, accessing the Care Everywhere activity (point #1 above) will change.</u>

- Rather than the Care Everywhere activity appearing automatically next to Chart Review, a Care Everywhere icon will appear in the storyboard, indicating the presence of outside records. Clicking on that icon will open the Care Everywhere activity to see the information.
- Outside encounters (point #2) and outside labs (point #3) will continue to be visible in the Chart Review tabs are they are now.

Please contact Diane Bauer, Research Compliance, if you need screen shots to help determine where this is located in Epic.

SMALL GROUP

2020 DATES AND TOPICS

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.

February topics:
Discussion of updated Continuing Review/Status Report/Final Closure and Protocol Summary Forms

February dates:
Feb 06, 2020 @ 11:00am
Feb 18, 2020 @ 2:00pm

2020 Schedule:
Mar 05, 2020 @ 11:00am
Mar 17, 2020 @ 2:00pm

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

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

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

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

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

IRBNET LIBRARY & WEBSITE

RESOURCE UPDATES

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.

Forms/guidances/web pages recently updated:

- Continuing Review/Status Report/Final Closure Form
- Protocol Summary Form
- Guidance for Consenting at Age of Majority

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.