OCTOBER 2020 | VOLUME 6 | ISSUE 3

HUMAN RESEARCH NEWSLETTER

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

MEET OUR NEWEST ANALYST!

MEGAN HINRICHSEN

Megan Hinrichsen has joined Children's as our newest IRB Analyst, having officially started in August, 2020! Megan holds a PhD in medical anthropology, concentrating in global health from Southern Methodist University.

She comes to us from Monmouth College in Illinois where she had been working as an assistant professor of anthropology and Chair of the Human Subjects Review Board. She brings with her experience as an educator (her favorite class to teach was called Health, Healing, and Ethics) and international researcher having done work in South America and West Africa on childhood malnutrition, food security, and international development. She works remotely from southern Minnesota where she lives with her spouse Kellen (director of the local history museum), their toddler Lars, and their adopted dachshund and two cats.

Please join us in making her feel welcome!

IN THIS ISSUE:

CLARIFICATION ON eCONSENT

RESEARCH COMPLIANCE

Currently, Children's has not approved electronic (digital) signature on consents. What some may be referring to regarding "eConsent" is the fact that we can email the consent to the subject/family via encrypted email--but, they need to be able to download the consent, sign it (unless a waiver of documentation has been granted by the IRB), and either fax it back, mail it back, or the study team can provide instructions to scan the consent and send via encrypted email. Another method is to provide the consent via a REDCap link, but the subject/family must be able to sign using a stylus.

Some researchers are doing this while they are actually seeing the patients and viewing the actual signature on a tablet via a stylus. In other words, Children's does not currently accept names typed in or some other method of digital signature. Children's does not yet have appropriate institutional policies nor the software to verify and confirm digital signatures. This pertains to all studies.

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!

PREPARATORY TO RESEARCH

HOW TO ACCESS

Research teams can complete a Preparatory to Research request form by going to Children's Connect, Service Requests, Data, and submit the request by choosing Research-Proposed as the request type. If you are on the Children's network, you will need to access Connect through Children's Citrix.

ADMINISTRATIVE SIGN-OFF

NEW CONTACT

Submission Sign-Off
Submission sign-off should be from a Children's administrative leader for areas affected by research. We want to know that research activities won't disrupt clinic or inpatient unit activities and for the research team to insure there wouldn't be any issues/limitations with the conduct of the study when a clinic or inpatient unit is involved.

Update for Ambulatory Sign-Off
Kelly Coy has been named Ambulatory Manager and will now provide administrative sign-off for research studies in this area.

OFFICE CLOSURE

HOLIDAY PLANNING

In observance of Thanksgiving, the IRB Office will be closed on Thursday, November 27 and Friday, November 28. The IRB Office will resume normal hours on Monday, November 30, 2020.

PROCESS UPDATES AND REMINDERS

TIPS FOR SUCCESS

Limitation on Multiple Pending Packages
Starting December 1st, the IRB Office will be limiting submissions with multiple pending packages. Once a Continuing Review/Status Report (CR) has been submitted and is pending, there should be no amendment submissions until the CR package is approved. Please plan accordingly. Exceptions that would be considered are (1) PI and staff change amendments that cannot wait until the CR package is approved; (2) changes that address unanticipated problems or affect subject safety; and (3) review timeline issues that cannot be avoided. Please contact the IRB Office at chwirb@chw.org before an additional package is submitted to discuss the rationale and to develop a submission and review plan.

Maintaining Blue and Black Text in ICF Templates
As the instructions in the ICF templates indicate, the blue instructional language should be kept blue when submitting consent forms for review. The intent of the color difference is so the analysts and reviewers can identify what language can be customized (blue) and what language is template language and should not be changed without prior approval (black). Starting December 1st the analysts will start enforcing this during pre-review and teams will be asked to restore the 2 colors if submitted with all black text. As a reminder, there is a request form available in IRBNet that can be emailed for review of any requested template language changes. Any black language changes should be reviewed and approved prior to submitting the package, and if approved changes are incorporated the request form should be included with this package.

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.

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

Join us for Open Office Hours! Open Office Hours are returning every Tue from 9:30 - 11:00 am via Zoom! Contact chwirb@chw.org to sign up.

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

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Also as a reminder, the IRB is the final authority on the language for consent documents presented to Children's subjects. Sponsors can request, with justification, changes to template language but it is not guaranteed those changes will be approved. Study teams can refer sponsors to the IRB Office for discussion of changes to our template language as needed.

Continuing Review Submissions Deadline
The IRB Office has been receiving late submissions for annual continuing reviews. We want to remind study teams of the expectation that Continuing Review submissions are submitted no later than 60 days before the expiration date. This deadline is noted in the automatic reminders about upcoming CRs (although you will have to calculate the specific date).

IRB Fees
As has been communicated previously via the Medical College of Wisconsin Office of Research, there is a new process for IRB Fee invoicing and payment. This communication relates specifically to studies reviewed and approved by the Children's IRB.

Effective October 1, 2020, study teams will be responsible for invoicing sponsors for the $7,000 IRB fee.

Determinations regarding which studies will receive invoices for IRB review fees will be made by the Children's IRB. Invoices created by the Children's IRB will be sent directly to the study team via e-mail from the TRU on the first day of the month following initial IRB approval of the study. If you have any questions about an IRB Review Fee invoice, please reach out to Lori Roesch at (414) 337-7705 for follow-up discussion.

An Additional Note from Medical College DOP Colleagues
Study teams will be responsible for invoicing sponsors for the IRB fee. These funds will now be deposited into and paid from your study project account. When the invoice is received from the IRB Office, this will be processed in iProcurement. An email will be coming out in the near future with additional details and instructions. Any questions regarding MCW processing (iProcurement, eBridge or CTA), please contact Theresa Kump at tkump@mcw.edu.

PEDIATRIC TRU

REMINDERS

Did you know?

The Pediatric Translational Research Unit (pTRU) provides resources outside of hands-on patient care for research. It is helpful to come talk to us early in your research protocol development.

Services include:

- Budget consultation
- Study monitoring for investigator initiated research
- IND/IDE submission support

Continues on next page.

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*.

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

- Preparation for audits (i.e., FDA)
- Research coordination training support
- pTRU orientation: learn how to run your study via the pTRU!
- Standardized onboarding toolkit for new hires
- EPIC training and support
- Mentor identification

Whenever you wish to initiate a study using the pTRU, or are otherwise considering using the pTRU, please contact Beth Gissibl or Jeff Crawford to further discuss.

Beth Gissibl
pTRU Manager
(414) 266-3994 | bgissibl@chw.org

Jeff Crawford
pTRU Ops Specialist
(414) 266-7254 | jcrawford@chw.org

INDUSTRY UPDATES

FDA UPDATES

- The U.S. Food and Drug Administration has published guidance on Institutional Review Board Review of Individual Patient Expanded Access Requests for investigational Drugs and biological Products During the COVID-19 Public Health Emergency.
- Remdesivir becomes first COVID-19 treatment to receive FDA approval.

EXTERNAL SITE UPDATES

COMING SOON

We know we've been sounding like a broken record, but our external site is in the process of being updated. We have been working hard to turn it into a valuable resource that study teams can use, even if they cannot access Children's Connect. Here's a sneak peek at some of the new content that's currently being developed:

- Glossary Page
- News and Announcements on the Home Page
- Emergency Use Page
- Exempt Research Determinations Page
- Human Subject Research Determinations Page
- Policies, Procedures, & Local Guidance Page
- Reliance Page
- Submissions Page ("How-To" Page)

Have suggestions on what else we should include? Let us know by emailing chwirb@chw.org!

RELIANCE REMINDERS

CHILDREN'S INSTITUTIONAL FORM

We wanted to remind study teams that the Children's Institutional Form is an important tool in the reliance request process. When this document is fully filled out and submitted at the time of the reliance request submission, we have noticed that it significant reduces the number of back and forth emails required between our team and research teams. This document is in addition to the Investigator Reliance Request form to answer Children's-specific questions. We have not mandated the use of this form, since there are some studies where the decision can be made without the form; however, we will be requiring it when necessary.

SMALL GROUP

REMAINING 2020 SESSIONS

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. The following are the remaining 2020 dates:

Nov 05, 2020 @ 11:00am	Dec 03, 2020 @ 11:00am
Nov 17, 2020 @ 2:00pm	Dec 15, 2020 @ 2:00pm

ADMINISTRATIVE UPDATES

NEW AND 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:

- New guidance: Getting Started with Children's IRB
- Updated guidance: Age of Majority

Children's Wisconsin
Human Research Protection Program/Institutional Review Board
Children's Corporate Center
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Children's Wisconsin
Kids deserve the best.