

FALL 2022 | VOLUME 8 | ISSUE 4

Human Research Newsletter

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

IN THIS ISSUE

CW IRB TRANSITIONING TO MCW PEDIATRIC
IRB - UPDATES & REMINDERS-2

eBRIDGE TIPS-3

REMINDERS-4

RELIANCE ON AN EXTERNAL IRB OTHER THAN
THE MEDICAL COLLEGE OF WISCONSIN-5

COMPLIANCE CORNER-5

SUBMISSION ASSISTANCE INFORMATION-6

NEW AND UPDATED DOCUMENTS IN THE
LIBRARY-6

QUESTIONS OR COMMENTS-7

EDUCATION OPPORTUNITIES-8

Children's Wisconsin IRB Transitioning to MCW Pediatric IRB - Updates and Reminders

In follow-up to previous information shared about transition of studies into eBridge, we would like to provide additional time sensitive information that will help clarify some questions that have come up

- **Background:** For studies that were identified as “Batch 1” projects (those with expiration dates ~November – April) and reported at the last continuing review to be in data analysis only, a transfer submission placeholder (“shell”) was not created in eBridge in anticipation that those projects would be closed in IRBNet. As a result, those studies will not be getting notifications from eBridge to submit a transition CPR. For these studies that have not yet been closed in IRBNet, they will still require a continuing review submission and IRB approval by Children's Wisconsin IRB or a closure report; reminders are continuing to be sent via IRBNet.
- **ACTION ITEM:** We ask that you proactively assess your research portfolio to account for ALL open studies and identify whether there is an approaching expiration date. If you have not received notification from eBridge for a Batch 1 study (those with expiration dates ~November – April), please reach out to us now via CWHRPP@childrenswi.org to discuss the situation and get direction about where to submit for renewal. If it is a study in data analysis only, we ask that you try to complete the project within the next year so that it doesn't need to be transitioned to eBridge.

To recap, all projects currently in data analysis (batch 1 AND batch 2) should be carefully assessed for the need to be renewed for another year versus closing them Batch 1. Studies in data analysis that must remain open will need to be transitioned as part of Batch 3 later next year. If there is a study that does not currently have a transfer submission shell built in eBridge, we can identify those and give you next steps.

Thank you all for your diligence as we work through this transition. As always, please feel free to contact us with any questions. Remember to use our new department email address: CWHRPP@childrenswi.org.



eBridge Tips

The importance of the “Update my Project”

As CW’s HRPP office has begun local context review we’ve noticed that some teams are not completing the “Update my Project” activity as part of transferring your project. When MCW created the shell of your project they only added the Principal Investigator and a primary contact. So in order to make sure everyone is listed, the team needs to make sure they click on “Update my Project” and add all team members. As part of the activity you need to fill in “Role on Project” and “SFI” for everyone listed. If these steps are not taken we cannot check if CITI has been completed or if there are any “Significant Financial Interest” that need to be addressed. By completing this before it gets to our review you reduce delays in the project approval.

Getting Started

Determine if your research project will be closing or continuing

(1) If your research project is in data analysis or manuscript preparation, then you should close your project and not transition it to MCW IRB. (Do not click the ‘Transfer Project’ button)

Project Closure Instructions:

When all research-related activities, including follow-up and data analysis of identifiable/coded data at this site are completed, or the project has been stopped or was never started, you should close the project in IRBNet with the CW IRB. An eBridge Administrator will administratively withdraw this PRO after the closure has been processed at CW.

or

(2) If your research project is continuing, then you should begin the institutionally required process to transfer your project to the MCW IRB using eBridge.

Transfer Project Instructions:

- Click the ‘Transfer Project’ button to complete the Continuing Progress Report (CPR) SmartForm and PRO SmartForm

- The PI will need to push the ‘Submit Application’ activity to route the submission through the review process.

- The CPR and PRO SmartForm must be received by the IRB at least 90 days before the expiration date for review.

- Click the ‘Update My Project’ activity to complete the information for the listed Primary Contact or change the Primary Contact.

- This step is required to avoid delays during the review process.

Adding Project Team Members:

- Click the ‘Update My Project’ activity to add team members to this research project

- If you cannot find the project team member in the list to select, then this person does not have an eBridge account. Please ask this person to complete an eBridge Registration form.

Please review the [Frequently Asked Questions](#) guide for assistance.

If you have questions, please contact the [eBridge Help Desk](#) or the MCW IRB Office at IRBOffice@mcw.edu or 955-8422.

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, JD, CIP at mmartin@childrenswi.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 Office Hours! Office Hours are returning every Tuesday from 9:30 - 11:00am via Zoom Contact chwirb@childrenswi.org to sign up.

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

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

REMINDERS

WHAT YOU NEED TO KNOW

When A Principal Investigator Leaves

When faculty serving as a Principal Investigator leave the institution, all research projects **MUST** be updated, before their departure, with the identified new PI. This should be done as soon as their departure date is known. If this is not done prior to the PIs departure, the research project has no PI oversight which is a violation of federal regulations and CW policy.

This update in PI should be done even when the plan is to close the study as there still needs to be oversight for compliance with the records retention policy, and in the event of any regulatory auditor quality review.

If the individual leaving the institution plans to have access to data at their new institution, the protocol should be updated describing the details and submitted with the PI change amendment so any reliance considerations can be addressed.

Please see compliance corner for additional information regarding EPIC access.

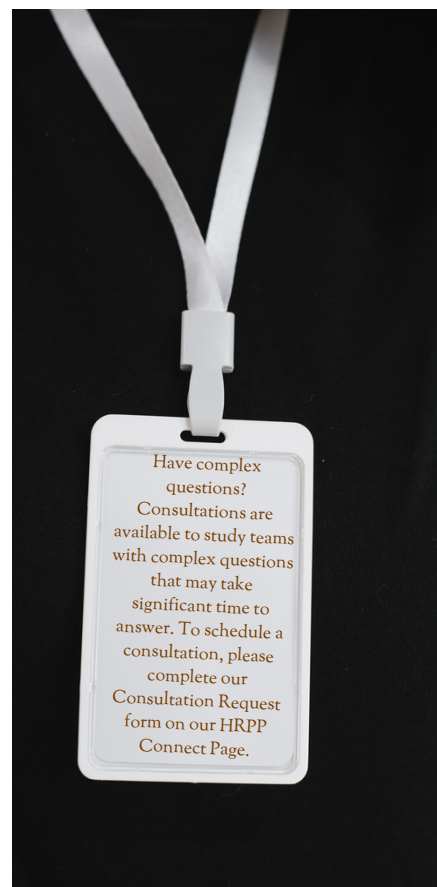
Reportable Events

For any active studies not yet transferred to the MCW Pediatric IRB, reportable events and new information should continue to be submitted in accordance with Children's Wisconsin IRB policy and guidance via IRBNet for review.

Once transferred, and for new projects involving Children's Wisconsin already open in eBridge, Reportable Events should be submitted via eBridge. These submissions will continue to be reviewed by HRPP staff at CW from the perspective of any local impact, local context considerations and CW will make recommendations to the MCW Pediatric Committees. Final determinations regarding whether an event is a UPIRSO or constitutes serious or continuing non-compliance will be made by the MCW Pediatric committees. However, CW HRPP may have additional recommendations or requirements regarding the CAPA, additional training, etc. related to conducting the research at CW.

The expectations of CW regarding reporting can be found in the Reportable Event Guidance:

<https://childrenswi.org/-/media/chwlibrary/files/medical-professionals/research/new-hrpp/guidance/reportable-new-information.pdf>



Reliance on an External IRB Other than the Medical College of Wisconsin

With the recent alignment of electronic submission systems with the Medical College of Wisconsin, the process for studies requesting reliance on an external IRB (an IRB other than MCW) has now changed. Please note that eBridge will be used to process study materials, but the reliance agreement will continue to be negotiated via CWReliance@childrenswi.org.

For all new studies requesting reliance on an external IRB, study teams should first submit their project in eBridge. The submission should include the overall approval letter, and approved versions of the protocol, recruitment/subject-facing materials, informed consent forms, and assent forms (this submission should not include local, customized materials).

After this submission has been reviewed by the Children’s Reliance Team, one of two letters will be issued. If Children’s is not agreeable to proceed with the reliance request, you will receive a letter that describes next steps. If Children’s is agreeable to proceed with the reliance, you will receive a letter with instructions on submitting local, customized materials.



COMPLIANCE CORNER

PUBLICATIONS AND EXTERNAL COMMUNICATIONS

Expired Tubes

Expired tubes for research activities should not be used because the tubes may have degraded additives (if there is an additive) and/or the vacuum seal on the tube may be decreased – thus preventing a proper fill.

The sponsor generally provides the tubes and should be aware of the expiration data as well. Always check the expiration date before your patient/subject arrives for the study visit.

Departed faculty/ departed students/ departed staff, unaffiliated individuals and Emeritus status

Departed faculty/staff/students, unaffiliated individuals, and Emeritus Professors do not fit into the definition of a member of our “work force” at Children’s Wisconsin. This definition can be found in the Privacy-Confidentiality, Patient Information Policy on Children’s Connect.

Individuals who are not members of the CW/MCW work force cannot have access to Epic.

Please refer any questions regarding this issue to Research Compliance.



Need Assistance With Your Submissions?

TIPS FOR SUCCESS

When preparing any new submissions and you come across any questions, please refer to one of the following locations for current FAQs, local guidance and Standard Operating Procedures (SOPs):
For CW studies still in IRBNet, you may access [Investigator Resources](#).

OR

In IRBNet, please select “Forms and Templates” on the left side of the page, then select “Children’s Hospital of Wisconsin Institutional Review Board, Milwaukee, WI – Documents for Researchers”. This provides a list of current guidances, forms and policies.

You can also contact the Children’s Wisconsin HRPP office at CHWIRB@childrenswi.org for help.
For MCW studies being submitted in eBridge, support is available:

- Use the [eBridge Service Request Form](#)

eBridge Help Desk:

414-955-8476

8:00 AM - 5:00 PM M-F

- Contact the MCW HRPP office at IRBOffice@mcw.edu

Note: SOPs and Guidances are always being updated; due to the Children’s Wisconsin Joint Venture agreement, both institutions are working together to align and update these policies. However, please refer to the appropriate institution’s resources to ensure you are using the most accurate, up-to-date information for your project. As always, if you have any questions, please email us at CHWIRB@childrenswi.org.

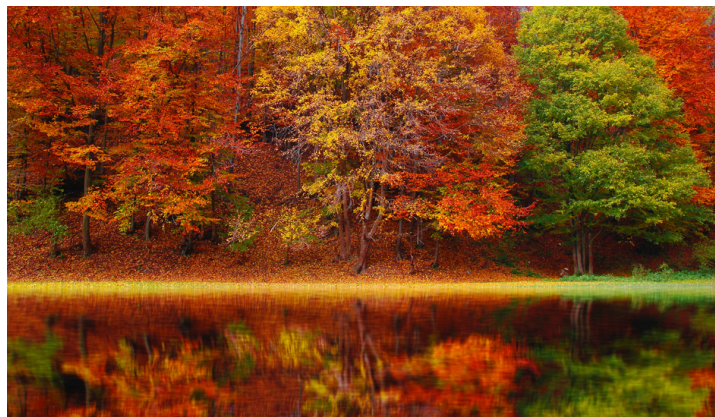
New and Updated Documents in the Library

[Guidance – CW Research Project Review by Safety Committees](#)

[Guidance – Process of Review by Imaging](#)

[Policy – Jurisdiction and Authority](#)

[Guidance – Departmental Sign off](#)



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 employees or providers who have competencies on file. Skills must be within the individual’s professional scope of practice.

HAVE QUESTIONS OR COMMENTS?

HOW TO BEST CONTACT THE HRPP/IRB

Your feedback is welcomed and valued; it is important to us to understand which areas we could improve upon or offer additional educational opportunities. For your convenience, there are a few ways to provide feedback:

- Through our main email inbox at CHWIRB@childrenswi.org
- By phone at 414-337-7133 (available 8:00am-4:30pm, after hours, please leave a message)
- Through our [website](#) (Our website offers an opportunity to provide anonymous feedback and your honest opinions are appreciated.)

To allow us to provide responses to your feedback, please use one of these methods. Attempting to communicate with one of our team members directly may cause a delay in response due to the volume of emails received. We look forward to hearing from you!



Artwork © 2001 by Don Mayne. All Rights Reserved. Unauthorized Duplication Prohibited. Contact: dontoon@aol.com

EDUCATION OPPORTUNITIES

AVAILABLE TO ALL RESEARCH STAFF



Small Group

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 held via Zoom. Topics and Zoom call-in information will be included in the Outlook meeting requests. Please feel free contact Jeff Crawford directly at (414) 266-7254 with any questions or to share any suggestions that you may have regarding discussion topics for future sessions.

Quarter 4 Dates

Date: Tues, Nov. 15th, 2022

Time: 2:00 PM

Topic: Epic: Review of New Workbench Report, Appointment Notifications, and HAM

Date: Thurs, December 1st, 2022

Time: 11:00 AM

Topic: Humanitarian Use Device (HUD) Discussion

Date: Tues, December 13th, 2022

Time: 2:00 PM

Topic: Humanitarian Use Device (HUD) Discussion

Quarter 1 Dates - 2023

Thurs, Jan. 5th, 2023 @ 11:00 AM

Tues, Jan. 17th, 2023 @ 2:00 PM

Thurs, Feb. 2nd, 2023 @ 11:00 AM

Tues, Feb. 14th, 2023 @ 2:00 PM

Thurs, March 2nd, 2023 @ 11:00 AM

Tues, March 14th, 2023 @ 2:00 PM



Kids deserve the best.



Introduction to the Children's Wisconsin IRB

This training session provides practical advice for working with the Children's HRPP Office to help ensure successful IRB submissions and ongoing (regulatory) study management. The goal of this program is to provide research staff – both coordinators and investigators – with important information on the workings of the Children's IRB, while sharing tips and tools for the safe, efficient, ethical, and compliant conduct of research. [Register for the next quarterly session!](#)

Office Hours

Join us for Office Hours! Researchers and study staff may sign-up for general questions and guidance that may be provided quickly (generally within 15-minutes or so). Office Hours are held weekly, every Tue 9:30–11:30 AM. Contact [Kristin Costello](#) to reserve your slot!

