

JULY 2022 | VOLUME 8 | ISSUE 3

Human Research Newsletter

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

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Human Research Protection Program Staff Announcement

The HRPP Department would like to welcome Analyst, Alexa Williams back to our team!

Alexa started her research career as a research nurse at a hospital in Orlando, Florida. She was hired as a research nurse for dermatology at Children's when she moved to Wisconsin and then was hired as an IRB Analyst. She joins us full time again after working with us on a casual basis for some time. Alexa has three kids ages 17, 15 and 8 and currently lives in Orlando. She still loves to visit Wisconsin, but only in the summer!

Fun Fact: Alexa is a trained dancer and taught at Milwaukee Ballet as well as performed in parades and shows at Walt Disney World!



Research Agreement with MCW - Frequently Asked Questions Link

The transition to the eBridge platform and the beginning of review by the new MCW pediatric IRB committees officially began on July 1st, 2022.

MCW and CW have created a list of [FAQs](#) regarding this transition. This will be a living document and updated as we receive additional questions. If your question is not answered by this document, please contact the CW HRPP Office at chwirb@childrenswi.org.



eBridge Reminders

- If Children’s Wisconsin resources are being used for the study, the discussion with those resources and confirmation that the resource can support the project should happen BEFORE submitting the project for IRB approval. During CW local context review we will be looking for documentation (uploaded into section 52 of the PRO SmartForm) from the applicable resources indicating they are aware of the project and can support it. Examples include (but may not be limited to)
 - Pediatric Translational Research Unit (pTRU)
 - CW imaging services (all uses of imaging – research only and standard of care)
 - CW laboratory and pathology services
 - CW Hospital units affected by the project – CW administrator sign off (see guidance: [Departmental Sign off](#))
 - CW pharmacy
 - CW Physical and Occupational therapy
 - CW Pulmonary Function Lab
 - Etc.
- Department (DOP) sign off v. CW administrator/department sign off
 - There is a button in eBridge to submit the project for “Departmental review”. This routes the project in eBridge to the Department of Pediatrics for review. This is different than getting department sign off from individual CW areas that may be affected by the research or have research activity happening in that space. This still requires documentation from that particular area (CW administrator) which should be uploaded into section 52 of the SmartForm – as has been expected for submissions in IRBNet.
- Formal protocol required for submissions
 - For new studies being submitted in eBridge, as well as studies transitioning at the time of CPR, a protocol is required to be included. The CW protocol summary should not be used as the protocol – rather a formal protocol template should be used. There are some [protocol templates](#) available on the CW CRI web pages. These are meant to be a guide to provide a starting framework but should be customized for the specifics of a project. This document should be uploaded into section 52 of the PRO SmartForm



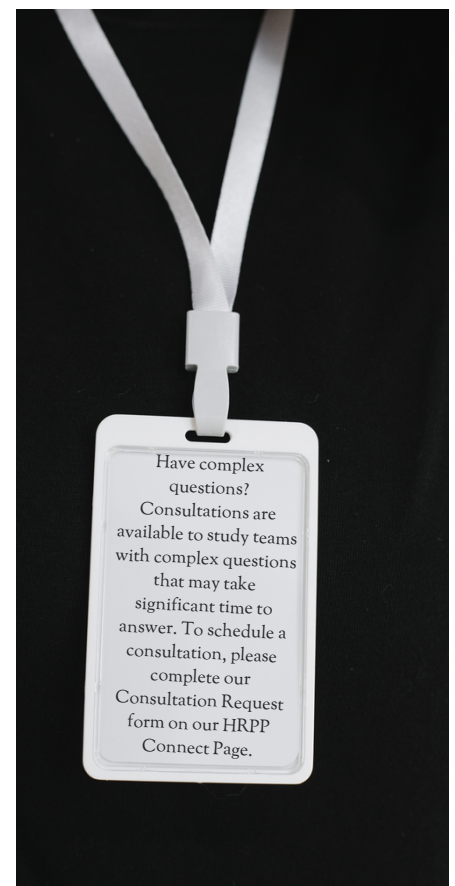
Reliance Questions? You can initiate the Reliance Request Process by visiting our HRPP Connect Page. Look under, “Reliance requests,” on our homepage. You can find insight to the reliance process by viewing our flow sheet.

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.

Children's Wisconsin Email Domain Transition

WHAT YOU NEED TO KNOW

During the past two years, efforts were made to rebrand Children's Hospital of Wisconsin to Children's Wisconsin. Publications, signage, websites and logos have been updated. One of the final steps in this transition is to change the email address domain from chw.org to childrenswi.org. This change will take place on September 6th.

The [July 14th Newsbreak article on Children's Connect](#), outlines what you need to know and what steps you need to take:

What do I need to know?

Your employee email addresses will automatically change from @chw.org to @childrenswi.org on Sept. 6. Your old @chw.org email address will redirect to the new addresses until Dec. 5.

What do I need to do?

Complete the following steps (depending on your role, you may not need to complete each step). If you need additional detail or instruction for each step, visit [this Connect page](#).

1. Update your email signature with a notice of the new address.
2. Notify non-Children's contacts that your email address is changing.
3. Identify department-specific website applications (not supported or owned by Children's) where you or your team might use your work email address as log in credentials or as the contact/verification email.
 - o Note: IS will be making updates to all emails within systems that use your Children's systems login credentials. (Example: AB123), like Epic, PeopleSoft and Bravo!. Your login credentials for these systems and applications will not change.
4. Contact professional organizations/groups you are a part of.
5. Update places you've promoted any Children's email address.
6. Identify any updates needed for printed materials.
7. Identify and update where you have emails listed on PDFs, forms or documents on Connect or the childrenswi.org.

The new domain email address are now active and set up as a secondary email address to the current chw.org email address, so employees may receive emails to both addresses. Starting September 6th, all emails will be sent from the childrenswi.org email addresses. Emails will be forwarded from the chw.org addresses for the following three months (through December 5th), then will no longer be active. Please be sure to update your email address accordingly.

If you have questions, please direct them to: comm@chw.org.



Email Addresses Associated with CITI and eBridge

As studies continue transitioning to eBridge from IRBNet, eBridge users should be conscious of what email addresses their CITI accounts are registered under, versus the email address used for their eBridge account. A feature in eBridge allows the system to update training expiration dates directly from CITI into eBridge. This occurs Wednesday and Sunday for new CITI users and is also updated nightly for any updates. To ensure this update occurs, there are a two options:



- If only your email address is entered in eBridge, the email address on the CITI account needs to be the same as in eBridge and needs to be spelled correctly, to ensure the updates occur. This enables the user to provide any email address, such as CW* or FMLH addresses and ensure training can be verified. (*For CW users, please be sure to update your email, using the new domain name in both eBridge and CITI – more information about this can be referenced in the article, also in this newsletter).
- The other option is to enter the CITI ID Number (which can be located on your CITI account), which will allow eBridge to update based on the CITI ID. (This may be helpful for those with multiple CITI accounts, to indicate which account training is located under).



If you have questions about your CITI Training uploading into eBridge, you may contact the eBridge Help Desk at help_ebridge@mcw.edu and provide your CITI ID number.

COMPLIANCE CORNER

PUBLICATIONS AND EXTERNAL COMMUNICATIONS

Corporate Compliance recognizes the value of providing information about research studies, however, prior to placing any articles or news bits in either internal communications or external communications, please forward the article to Corporate Compliance ([Tom Twinem](#) and [Diane Bauer](#)) for review.



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.

At The Movies!

More than a decade in the making, [THE HUMAN TRIAL](#) follows a groundbreaking clinical trial that peels back the headlines to show the sweat, passion and sacrifice behind every breakthrough cure. In 2011, Lisa Hepner and her husband Guy Mossman heard about a radical stem cell treatment for diabetes, a disease that shockingly kills more than five million people each year. Driven by a desire to cure Lisa of her own type 1 diabetes (T1D), the filmmakers were given unprecedented, real-time access to a clinical trial – only the sixth-ever embryonic stem cell trial in the world. What follows is an intimate journey with the patients and scientists who put themselves on the line to be first.



Departmental Researcher and Research Personnel Information

As a reminder, when any new researchers or staff members join your departments and divisions, please be sure to add them to your team. Adding a study team member requires updating all relevant study documents, including the registration page and submission of an amendment form in IRBNet for all projects not yet transitioned to eBridge. For new studies in eBridge, please refer to [MCW's SOP](#) for Amendments. New study team members should not be conducting any study-related activities until the staff change has been approved.

In addition:

- Contact the CW HRRP office at chwirb@childrenswi.org to add them to our distribution list.
- Utilize the [onboarding tools](#) available to orient new staff who will be working on studies conducted at Children's Wisconsin.

Principal Investigators (PI) that have researchers or study team members that are leaving the institution, may submit an amendment in IRBNet or update the staff page in eBridge, to notify the IRB of their departure. For studies still under Children's Wisconsin IRB oversight, Amendments may be submitted for staff changes or change of Principal Investigators that cannot wait until the next Continuing Review (CR), often, researchers submit an amendment to add and remove staff members with the same submission. During the CR process, members may be removed from the team without submitting an amendment, this information is to be included in Section 7 of the [CR Form](#). Removing research personnel also includes updating all relevant study documents, including the registration page and revoking IRBNet access, if applicable. Once removed from a study, former research personnel should not be conducting any study-related activities or have access to study data.

When individuals are leaving the institution (CW or MCW) and want to remain on the project, wishing to remain on the project need to consider:

- Will they have access to data? If so, what type of data?
- Will they retain faculty appointment or hospital privileges?
- Should they be removed from study?

Please confer with the CW HRRP office and CW Corporate Compliance for guidance.



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.

Amending An Exempt Study

When you receive an Exempt Determination Letter from CW HRPP Office, the first item under ‘Reminders’ is:

Any changes to the scope or intent of the project must be reviewed by the Children’s Wisconsin IRB/ HRPP office prior to implementation to see if the changes impact the exempt determination.

Investigators who have exempt studies really should only submit amendments that could change the scope of the study. If the changes you are considering do not change the scope, then make sure you document the change in the research study folder or binder, but you do not need to submit an amendment. If the amendment is needed in the future, then submit all changes at that time.

Examples, not all inclusive:

<i>Update</i>	<i>Amendment Required?</i>
Changing research staff	NO
Changing PI	YES
Adding a variable collected that is not collecting additional PHI or new sensitive information, and is within intent of what was approved	NO
Collecting additional data that could be outside the original scope of the protocol	YES
Adding a cohort of subjects requiring special protections	YES
Updating the contact information of the study team members on patient documents	NO
Adding a new arm to the study	YES
Sending data to a new collaborator	YES
Adding interaction with subjects, when there was previously no interaction	YES
Adding a new department where prospective enrollment or study activities happen	YES



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!



ADMINISTRATIVE UPDATES

NEW AND UPDATED RESOURCES

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

Recently released and updated policies, guidance, and forms:

- [Guidance - CHW Research Project Review by Safety Committees](#)
- [Guidance - Process of Review by Imaging](#)
- [Jurisdiction and Authority Policy](#)
- New [Reliance Process](#) This is the general policy regarding deferrals of the IRB oversight of research to any IRB. This replaces the policy CRI - IRB - Projects Deferred to National Cancer Institute Central IRB (NCI CIRB). When engaged in multi-site research, research involving external collaborators, or research that is otherwise under the jurisdiction of more than one IRB, Children's Wisconsin acknowledges that each organization is responsible for safeguarding the rights and welfare of human subjects and for complying with applicable federal regulations. Children's Wisconsin may choose to review the research in its entirety, only those components of the research Children's Wisconsin is engaged in, rely on the review of another qualified IRB, or make other arrangements for avoiding duplication of effort. When Children's Wisconsin is the prime awardee on an HHS grant, it will ensure that at least one IRB reviews the research in its entirety.



Regardless of which IRB is designated to review a research project, Children's Wisconsin is responsible for the conduct of the research in which it engages. Research reviewed by external IRBs remains subject to review, approval, and oversight by Children's Wisconsin and must adhere to all applicable policies, procedures, and requirements, including those of the Children's Wisconsin HRPP. In addition, the HRPP/IRB office staff will review the information provided and verify that CITI training, COI review, and any other applicable approvals or requirements have been completed. HRPP/IRB office staff will ensure any necessary local context information has been provided to the reviewing IRB in accordance with the reliance agreement.

This document describes in more detail, the roles and responsibilities of both the relying organization and reviewing IRB. Please take some time to review and understand. It will also help you understand the new relationship with the MCW Pediatric IRBs and the Children's Wisconsin HRPP.



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 3 Dates

Thurs, Aug 11, 2022 @ 11:00 AM

Tues, Aug 23, 2022 @ 2:00 PM

Thurs, Sept 1, 2022 @ 11:00 AM

Tues, Sept 13, 2022 @ 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!

