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Human Research Newsletter

A quarterly newsletter from
The Children's Wisconsin HRPP/IRB

IN THIS ISSUE

ONBOARDING INFORMATION–2
HRPP STAFFING UPDATES–3
CITI TRAINING INFORMATION–3
CONTINUING REVIEW DATES–3
RESEARCH AFFILIATION AGREEMENT UPDATES–4
TRANSITION TIMELINE–4
HRPP VERSUS IRB–5
SUCCESSION PLANNING–5
REMINDERS–6
PRE-REVIEW RESPONSES–6
EDUCATION OPPORTUNITIES–7
ADMINISTRATIVE UPDATES–8

ONBOARDING FOR NEW CLINICAL RESEARCH COORDINATORS

REMINDERS FOR STUDY TEAMS

New CRCs that will be coordinating studies being conducted at Children's Wisconsin should work with their managers to complete the Children's Wisconsin onboarding process. The checklist can be found here: https://train.mcw.edu/ResearchTraining/cw.html. This is intended to educate new employees about Children's/MCW's research policies and procedures. There is a lot to learn about the research processes at Children's. This is a tool to assist you with some key components that help set you up for success! Our goal is to spread this information out over your first 120 days to make it more manageable.

Additionally, the Children's HRPP Office continues to offer an education session, Introduction to the Children's IRB. This training session will provide practical advice for working with the Children's HRPP Office to help ensure successful IRB submissions and ongoing (regulatory) study management.

- Explore policies and operations of the Children's HRPP/IRB Office
- Learn best practices directly from HRPP Staff
- Overview of the entire Children's IRB lifecycle

Register online

Date: Held quarterly (next session is slated for March 30, 2022)
Time: 8am – 12:00pm
Location: Zoom

HRPP STAFFING UPDATES

Kristin Costello recently joined Children's Wisconsin as the Administrative Assistant for the HRPP Office. She is being trained and has taken over many support functions, including calendar management for the team. She is enthusiastic about learning new responsibilities as they are identified. Kristin comes to us from Curative in the Adult Day Program, and before that, the Medical College of Wisconsin, working with medical students. Kristin is currently completing an associate's degree in Human Services from Milwaukee Area Technical College, graduating in spring of 2022 and will transfer to UW-Milwaukee to complete a BS in Social Work. In her free time, she enjoys reading, spending time with her four dogs and going on road trips to discover fun, new places, and activities.

Rebecca Sandborg joined the HRPP as an IRB Analyst in December 2021. She has an extensive background in basic science research, clinical research administration and research compliance, working most recently in research compliance at Henry Ford Health System in Detroit, Michigan and Oakland University in Rochester, Michigan. She currently lives in Michigan and will be working remotely with the HRPP team and the Children's research community. When not working, Becky enjoys cycling, spending time with friends and with her beloved dog, Gordy. She is thrilled to have the opportunity to be a part of the Children's research community.

Please join us in congratulating Brandon Woodruff on being promoted to IRB Analyst! Brandon is in the process of transitioning much of his previous workload to Kristin Costello and has already begun working with study teams on their research projects. Brandon has been with Children's for about three years and is a senior at George Washington University finishing a BS in Clinical Research Administration.

Welcome to our new staff and congratulations to Brandon!

CITI TRAINING AT TIME OF STUDY RENEWAL

CONTINUING REVIEW

We would like to remind study teams of the importance of making sure the training on file with the HRPP is kept up to date. This includes ensuring that any CITI training is renewed prior to expiration. The CITI program does send reminders to users when their training is coming up for renewal.
To better ensure that this is up to date, the HRPP Office will be checking for completed CITI training for all team members listed on the registration page at initial submission, staff change amendment AND at subsequent continuing review/study renewal. This will begin effective February 14th, 2022. If there are any study team members with expired CITI training, the package will not be reviewed until this is current. Please consider a tracking mechanism to address this prior to submitting the CPR.

CONTINUING REVIEW DEADLINES

BEST PRACTICES

The HRPP is reminding study teams of the expectation that continuing review submissions are to be submitted no later than 60-days before the expiration date. Does this mean you need to wait until the 60 day mark to submit? No. In fact, especially for studies that are greater than minimal risk, submitting by 90 days prior to the expiration date is preferred. These dates enable the HRPP Office to pre-review packages prior to the expiration, and, if necessary, assign to an IRB agenda. Having a time 'cushion' hopefully allows any questions to be answered prior to expiration. Failure to submit the continuing review package by the 60-day deadline may result in a lapse in IRB approval and may require submission of a reportable event and CAPA that addresses the late submission.

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@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 Office Hours! Office Hours are returning every Tuesday from 9:30 – 11:00am via Zoom Contact chwirb@chw.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.

RESEARCH AFFILIATION AGREEMENT UPDATES

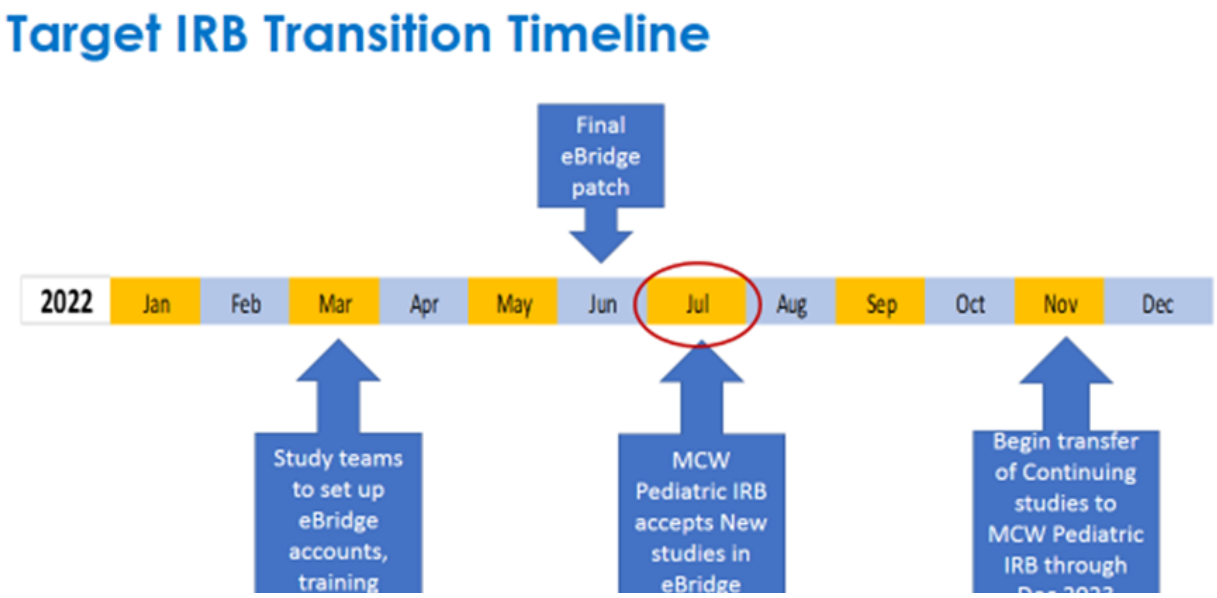
IRB TRANSITION PROCESS

- As you know, we are working with MCW on a plan to transition the majority of research studies being conducted at Children's to the new MCW pediatric IRB for oversight. This process will involve moving active research studies to the eBridge platform. There will be detailed updates and training provided over the next few months before the go-live date. Investigators will be notified by MCW when eBridge is ready to accept your Continuing Review/Continuing Progress Report ("CPR") and updated study application.

- In preparation for the transition, the Children's HRPP Office needs to provide to the MCW IRB information about all active studies so work can begin to build a shell for the project in eBridge. If not already done, we will need the PI to identify ONE study coordinator or individual who will serve as the primary contact for each active study, and send the name to us by February 18, 2022. If an individual is not identified, the default will be the PI. This means that the PI will be the ONLY person with access to the study shell in eBridge and will be responsible for submitting the required CPR and updated study application when this becomes due.

- You can reach out if you have specific questions about this request via chwirb@chw.org.

- **When submitting a new study between now and the transition to eBridge, please include a cover memo that indicates ONE primary contact person for the project going forward. If no primary contact is identified, this will default to the Principal Investigator.**



HRPP VERSUS IRB

As a reminder, with the research affiliation agreement between MCW and Children's, the scope of services provided by the Children's Research Institute will continue. This includes the Pediatric Translational Research Unit; Grants Development Office; Biostatistics/Bioinformatics; Cores such as histology, confocal imaging, and flow cytometry; research space and equipment; and Nursing Research.

As part of the Master Research Affiliation Agreement, an Institutional Review Board (IRB) Services Agreement was executed. Under this agreement, Children's maintains its Human Research Protection Program (HRPP) and delegates the IRB of record function to MCW. Children's may delegate to a third-party IRB in certain circumstances, and Children's HRPP will continue to make research versus quality assurance determinations. The agreement sets forth requirements for pediatric IRB committee composition.

The IRB committees are one part of an HRPP program, and Children's will continue to have an HRPP working with the MCW pediatric IRBs for review and oversight of research activities occurring at Children's. The MCW pediatric IRBs will be the IRB of record, while local context review and other HRPP functions will remain with Children's.

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.

SUCCESSION PLANNING

The Principal Investigator (PI) is ultimately responsible for all conduct of a research study. Even when responsibilities are delegated to other investigators, the PI is considered the leader of the team and bears the oversight. In IRBNet, the PI needs full access to be able to review, make changes and manage their study. Study teams should always have a back-up plan for when a PI will be gone for an extended period of time; however, when it is known that the PI will be leaving permanently, it is CRITICALLY important that his or her active studies be transferred to another investigator (or are formally closed if allowable) as soon as possible. While the HRPP understands that time of PI transition is quite busy, a plan should be formed as quickly as possible by a department to prevent lapses in oversight, especially for studies where human subjects are participating actively with interventions or follow-up care.

Creating a list of all studies the PI has currently open, organizing that list according to which studies have active interventions/follow up, which have ongoing data collection, which are in data analysis only, and which are only dealing with data storage can help the department stay on top of the transition and prioritize the urgency of the PI changes. It is ALWAYS best practice to transition to the new PI BEFORE the current PI leaves the institution. This enables a smooth transitions for subjects, their data, and allows for any oversight questions to be answered before the leaving PI is no longer available. Any plans for transferring/sharing data (where possible) will take even longer to put into place, so formal transition should not be delayed pending these activities.

REMINDERS

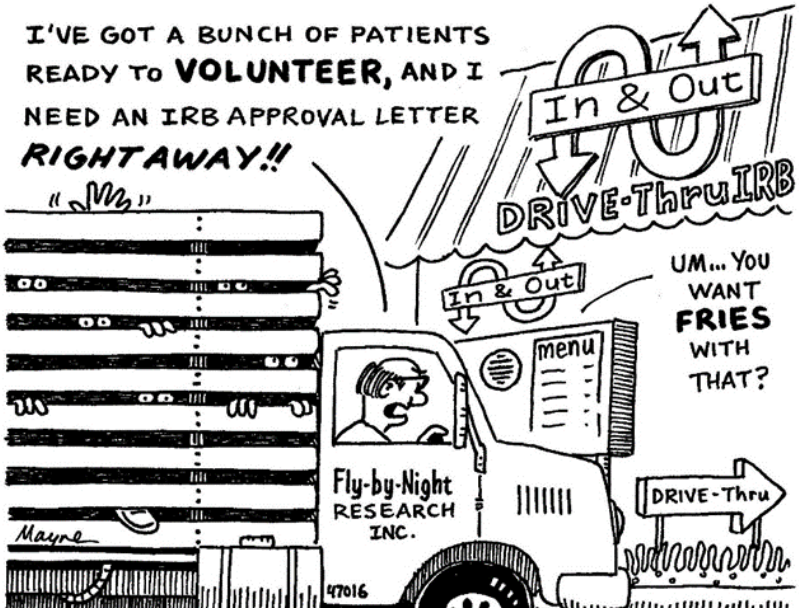
TIPS FOR SUCCESS

- Requested modifications to a research study should be summarized on the Amendment Form. Avoid vague statements such as “changes requested by the sponsor” or “changes requested by the IRB.” Also, please refrain from cutting and pasting lengthy details from the sponsor. Summarize those changes on the form, and include the sponsor’s document in the submission.
- When changing the Registration Page in any way or adding it to any package, please check that Section XII is filled out since new checkboxes were recently added.
- Ensure the appropriate CITI training is already completed and any NEW investigators have signed off on the package prior to submitting a staff change amendment.

PRE-REVIEW RESPONSE LETTERS

POINT-BY-POINT IMPORTANCE

During pre-review, there are often a number of items to address within study documents and sometimes there are simply questions that need to be answered by the study team. Having point-by-point response cover memos during the pre-review process enables our reviewers to know which items were addressed, which items may still need additional clarification, and shows us the history of the pre-review process. Be sure to include these memos, if instructed, during pre-review. Also, do not write over/replace the previous cover memos (if multiple unlocks occur) since valuable information about the review process is present in each one. Keep each cover memo in the package and add new ones as necessary.



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.

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 1 Dates

Thurs, Feb 2, 2022 @ 11:00 AM
Tues, Feb 15, 2022 @ 2:00 PM

Thurs, Mar 3, 2022 @ 11:00 AM
Tues, Mar 15, 2022 @ 2:00 PM

Quarter 2 Dates

Thurs, Apr 7, 2022 @ 11:00 AM
Tues, Apr 19, 2022 @ 2:00 PM

Thurs, May 5, 2022 @ 11:00 AM
Tues, May 17, 2022 @ 2:00 PM

Thurs, Jun 2, 2022 @ 11:00 AM
Tues, Jun 14, 2022 @ 2:00 PM

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!

Office for Human Research Protection (OHRP) Luminaries Lecture Series:

Use of eConsent in Human Subjects Research

Megan Doerr, MS, LGC, principal scientist at Sage Bionetworks delivered a lunch-and-learn webcast for OHRP in January 2020. Ms. Doerr described various forms of e-consent, the importance of accessibility and readability, the use of apps for research purposes, and shared case studies to explore ways of approaching e-consent to satisfy regulatory requirements and ethical standards. Sage Bionetworks posted this video for public distribution and is available here.

Additional resources:

- Review the FDA/OHRP 2016 Guidance on Use of Electronic Informed Consent: Questions and Answers
- Review the OHRP featured video, "Simplifying Informed Consent"

ADMINISTRATIVE UPDATES

NEW AND UPDATES 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:

- Updated Guidance: Corrective and Preventative Action (CAPA) Plans
- New Form: Exempt Research Protocol
- New Form: Request for Exempt Determination
- Updated Form: Continuing Review/Status Report/Closure Form
- Updated Form: Reportable Event Log
- Updated Policy: Exempt Studies
- Updated Website: External website features new resources

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.