OCTOBER 2021 | VOLUME 7 | ISSUE 4

HUMAN RESEARCH NEWSLETTER

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

IN THIS ISSUE

RESEARCH AFFILIATION AGREEMENT

RESEARCH PARTNERSHIP

In July, a research affiliation agreement was negotiated between the Medical College of Wisconsin and Children's Wisconsin which, among other things, states that the Children's Human Research Protection Program (HRPP) will rely on the MCW IRB pediatric review committees to review, approve, and monitor human subjects research. Children's will continue to operate our HRPP office and will provide support services. All local context considerations will remain the responsibility of the Children's HRPP. Children's HRPP will also consider requests to rely on other IRBs as appropriate.

Below, we describe a partial list of changes that will occur when the transition is complete.

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!

Children's HRPP will remain responsible for:

- Oversight of research activities within Children's space
- Approve reliance requests
- Manage local context when relying on other IRBs
- Provide education
- Conduct quality assurance activities related to studies in Children's space
- Manage COI
- Manage investigational products
- Community outreach

Under the research affiliation agreement, Children's Corporate Compliance will continue to have oversight of research billing, COI, all HIPAA determinations, and use of Children's facilities for research, etc., so the affiliation agreement does not change the role of Children's Research Compliance.

MCW's IRB will, in the future:

- Develop pediatric-focused IRB committees
- Be the primary IRB relied upon by Children's HRPP for new and existing studies
- Have the authority to suspend or terminate approval for studies under its oversight
- Conduct quality assurance activities related to studies under its oversight

The details of the transition are being worked out between MCW and Children's HRPP/IRB Offices. We anticipate a gradual transition of studies beginning in March 2022 that will take at least one year. As details are established, we will communicate to our researchers via a shared platform. There are no changes currently, so please continue to work with the HRPP/IRB as you are currently.

Lori Roesch
Research Integrity Manager
Children's Wisconsin HRPP

Ryan Spellecy
Director, MCW HRPP
Assistant Provost for Research

UPDATED FINANCIAL COI TRAINING

REQUIRED TRAINING FOR MEDICAL COLLEGE EMPLOYEES

This updated training requirement only applies to employees of the Medical College of Wisconsin.

Financial Conflicts of Interest in Research (FCOI-R) Training has been updated to reflect revisions to the MCW FCOI-R Corporate Policy, effective August 15, 2021. Significant changes include:

- Scope has been expanded to include industry sponsors, the National Science Foundation, non-PHS sponsors and other federal funding agencies as required by award or policy
- Dollar threshold for equity in a publicly traded entity has been revised
- A higher dollar threshold has been established for FCOI with regard to industry-sponsored research

The FCOI-R policy and federal regulations require that FCOI-R training must be renewed every four years **and** any time MCW revises this policy. Because the FCOI-R policy was revised on August 15, you are asked to retake FCOI-R training and update any SFI disclosures at this time. Training must be completed no later than December 31, 2021.

What you need to do: Complete FCOI-R training by 12/31/2021, even if it has not yet been 4 years since you last completed the training.

Don't wait until you have a submission deadline to take this training. New funding proposals or continuations of currently active awards submitted on or after 1/1/2022 will be held at the "Agree to Participate" step and will not be processed until the updated training has been completed.

The updated training is accessible in eBridge. Instructions on how to complete the new training can be found here: https://train.mcw.edu/ResearchTraining/compliance-courses.html

Questions can be directed to:

Matt Richter
Senior Manager of Research and Academic Compliance
mrichter@mcw.edu

BACK TO BASICS

IRB ACTIONS ON HUMAN SUBJECT RESEARCH

OHRP (Office of Human Research Protections – HHS) and the FDA interpret "actions taken by the IRB" (also called "IRB actions") to refer to any vote taken by the IRB related to a proposed research activity.

OHRP and FDA regulations (45 CFR 46.109(a); 21 CFR 56.109(a)) require that an IRB review and have the authority to:

- Approve: In order to approve research covered by the regulations in 45 CFR part 46 and/or 21 CFR part 56, the IRB must determine that all of the criteria for IRB approval of research are satisfied (45 CFR 46.111; 21 CFR 56.111).
- **Require Modifications** (to secure approval), or
- **Disapprove** all proposed research activities covered by the regulations
  - This generally means that the project, as proposed, will not meet the regulatory criteria for approval OR
  - There is some facet of the research which makes it unacceptable to conduct at the institution
  - The Institutional Official can disapprove a study that has been approved by the IRB, but cannot approve research that the IRB disapproved
  - The expedited reviewer can approve research without convened board review, but cannot disapprove research without a convened board review

Additionally, the IRB or institution may develop a range of other allowable actions the IRB may take when reviewing proposed research activities (e.g., approve with conditions, defer a decision until additional information can be obtained). The IRB's written procedures describe the range of possible actions the IRB can take.

Defer/Table: When an IRB tables, or defers, a decision on a study, this is not a disapproval. This means that the submission did not have enough information for an IRB to determine that the regulatory criteria for approval have been met. A resubmission with additional information or clarifications may allow the IRB to reach an approval determination.

Suspension/Termination: Both OHRP and FDA regulations authorize an IRB to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects (45 CFR 46.113; 21 CFR 56.113).

- The Institutional Official or an IRB Chair may decide to suspend or terminate research for safety reasons.
- If there is a decision to suspend or terminate the study that occurs outside of a convened IRB meeting this gets reported to the convened IRB.

Continues on next page.

Other determinations that an IRB may make:

- Non-significant risk determination for medical devices being used in research
- Whether non-compliance rises to the level of Serious or Continuing Non-compliance
- Whether an adverse event meets the criteria for a UPIRSO (Unanticipated Problem Involving Risk to Subject or Others)

REMINDERS

TIPS FOR SUCCESS

- It is always good practice to include the version dates of documents in the electronic document titles when saving the document before uploading to IRBNet, or in the description in IRBNet. This helps to verify at the time of submitting that wrong versions are not included with a submission. Additionally, sponsors often request that the list of documents reviewed by the IRB be delineated in the decision letter, clearly noting the version date of the documents. You can control what is included in IRB approval letters by carefully naming your documents.

- Use the compare documents feature when getting edited consents back from the sponsor to avoid missing a sponsor change that may revert IRB required language or changes back to their model consent language, as well as verifying they did not change language required by the Children's Wisconsin HRPP or by regulations.

- When the IRB approves a project, they are approving what is described in the protocol submitted for review. It is important to be sure that any other documents (such as case report forms, consent documents) do not contain different or additional information than what is described in the protocol. Federal regulations do not require IRB review and approval of other study materials such as case report forms, lab or pharmacy manuals, Investigator's Brochures etc. If something is not described or included in the sponsor protocol, then it was not reviewed and approved by the IRB and should not be conducted.

- Children's Wisconsin HRPP policy requires the Continuing Progress Report to be submitted no later than 60 days before the project expiration date outlined in the IRB approval letter. Submitting a Continuing Progress Report past the deadline (less than 60 days before the project expiration date) without prior discussion and approval from the HRPP office constitutes non-compliance and a Reportable Event package with a CAPA must be submitted to the HRPP office.

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.

NEW IND TRAINING REQUIREMENT

UNEXPECTED SUBJECT ENROLLMENT

This month, a new training requirement for sponsor-investigators goes into effect for investigators who hold an IND from the FDA. This requirement is only for investigators, not study staff; however, anyone is welcome to take the training. This training is required for single-patient treatment INDs as well, but not for Emergency Use requests.

We are requiring this training **only** for NEW submissions at this point in time. For anyone with an active IND, they would not need to complete the training until they decide to submit another IND to the FDA.
It takes about 1 hour to complete each training, and there is an assessment quiz at the end of the webcast. With successful completion of this course, the investigator will receive an email notification confirming completion of the coursework. A copy of this verification should be uploaded into any new project packages in which the investigator has applied for and received an IND from the FDA.

Here is the link to the training, found on train.mcw.edu:

https://train.mcw.edu/ResearchTraining/hsrp-courses.html

2022 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.

2021 Quarter 4 Dates
Thurs, Nov 4, 2021 @ 11:00 AM
Tues, Nov 16, 2021 @ 2:00 PM

Thurs, Dec 2, 2021 @ 11:00 AM
Tues, Dec 14, 2021 @ 2:00 PM

2022 Quarter 1 Dates
Thurs, Jan 6, 2022 @ 11:00 AM
Tues, Jan 18, 2022 @ 2:00 PM

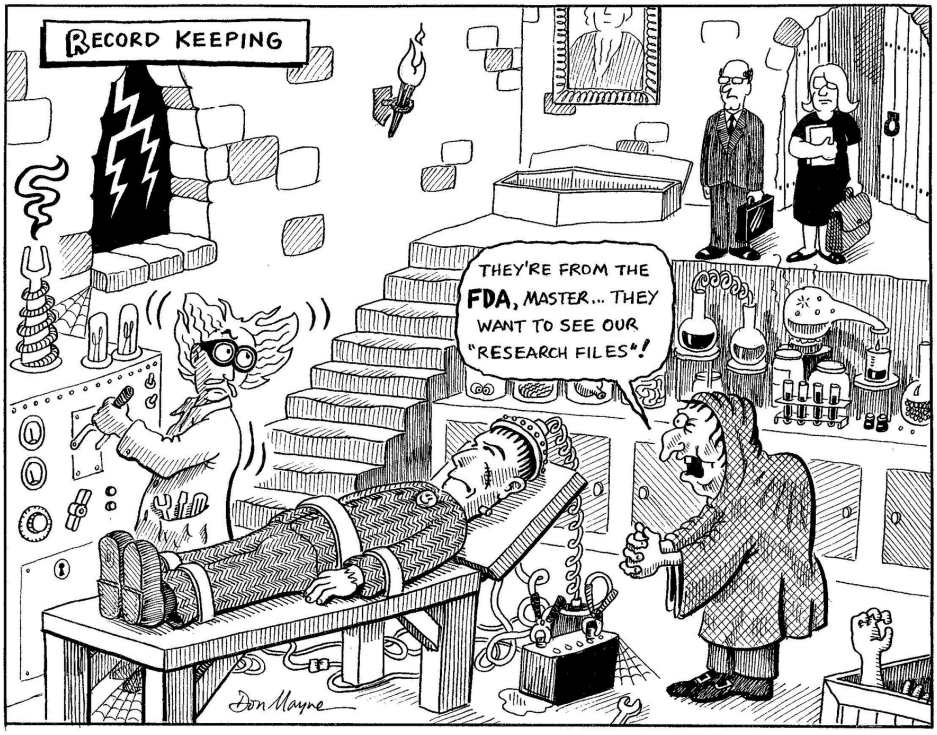
Thurs, Feb 3, 2022 @ 11:00 AM
Tues, Feb 15, 2022 @ 2:00 PM

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

EXEMPT RESEARCH

NEW AND UPDATED RESOURCES

Some Children's research teams have been noticing more unlock messages during pre-review that indicate the study may qualify for exemption and to update the submission accordingly. While the updated policy regarding exempt studies, new exempt research protocol template, and new request for exempt determination form (available in IRBNet, under Forms and Templates) have been available for a few months (as communicated in the July newsletter), many have not yet had the chance to get used to the updates. According to our updated policy, we applied the 2018 common rule to studies being submitted after June 29, 2021. There were changes in the 2018 common rule to the exemption categories, including the addition of a category that enables some formerly considered expedited chart review studies to now be considered for exemption. We are doing our best to catch as many of those studies submitted to us that could qualify for exemption as possible, but we may miss a few. The benefit of teams requesting this or us catching and requesting this type of review, is that if exemption is possible, no further IRB oversight is required after the initial review (unless the study scope or intent changes).

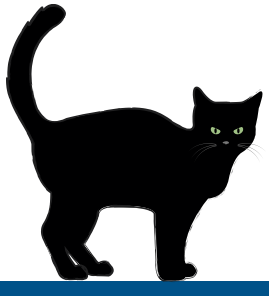


Join us for Office Hours! Office Hours are returning every Tue from 9:30 - 11:00 am via Zoom! Contact chwirb@chw.org to sign up.

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

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.



2022 Introduction to the Children's Wisconsin IRB
This quarterly training session provides practical advice for working with the Children's HRPP Office to help ensure successful submissions and 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.

Session dates for 2022 will be available shortly. When available, you can register here!

Virtual Office Hours
Join us for Virtual Open 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 Brandon Woodruff to reserve your slot!

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:

- New Guidance: Protocol Feasibility Assessment Tool
- New Guidance: Tool to Assist with CRC Transition
- Updated Form: Continuing Review Form
- Updated Form: ICF Template Change Request Form
- Updated Form: Exempt Determination Request Application