APRIL 2021 | VOLUME 7 | ISSUE 2

HUMAN RESEARCH NEWSLETTER

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

IN THIS ISSUE

MEET OUR NEWEST ANALYST

MEGHAN "MEG" HAMMOCK

Please join us in welcoming Meg to Children's! Meg comes to our HRPP with 8 years of IRB experience, primarily working at the University of Texas at Austin in the Office of Research Support, as well as serving as a consultant. She holds a Bachelor of Arts in Literature degree and certifications in medical billing and coding.

She and her husband still reside in the Austin, Texas area, and will be working in a remote capacity from home. Again, please join us in welcoming her to our team!

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!

COMPLIANCE CORNER

REMINDERS FOR RESEARCHERS

Reminders about HIPAA Waivers:

- HIPAA Waivers pertain to the study activities in its entirety. A full Waiver of HIPAA Authorization is only granted if the study team will never seek HIPAA Authorization (retrospective review), thus the name “full.”
- A partial Waiver of HIPAA Authorization is exactly what it says it is, “partial” because it represents part or some of the study activities; for example, a partial wavier for screening, partial waiver for a portion of the study that may be retrospective reviews (and HIPAA Authorization is never obtained from this population), or a partial waiver to maintain PHI at age of majority.
- Research teams can submit one Waiver of HIPAA Authorization and put multiple uses on one waiver. This should be done when initially submitting a new study to cover all the bases and addressing the issue in the protocol summary.

Reminders about recruitment practices:

- The Children's HRPP has recruitment guidelines that can be found in the Guidance – Recruitment for Human Subjects Research. There are certain methods of recruitment that are not allowed at Children's. For example:
  - "Cold calling” potential subjects (calling or approach by a staff member/research team member that does not have a prior treating relationship with that potential subject).
  - Letters coming directly from research staff, rather than a treating provider.
  - Plans to contact potential subjects if the research team does not hear from them rather than waiting for the potential subject to contact the research team.

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Compliance policies and forms:

- Children's Corporate Compliance is currently working to either update or create new policies and has revised some forms.
  - The Research-Conflict of Interest Policy is being revised to clarify procedures.
  - A new Epic Care Everywhere policy has been created and will be posted soon.
  - The Waiver of HIPAA Authorization form has been revised to provide clarification and support the current Children's Research Record Retention policy. This new form will be posted soon.

REMINDERS

REMINDERS ABOUT AVAILABLE RESOURCES

Submission Documents Checklist:
We have been getting questions about what documents should be included in various package types, so we want to remind everyone that there is a checklist for several different types of submissions, including shadow submissions for studies that have been ceded to an external IRB. This is a guideline – and lists many possible documents that a particular submission may need. Not every document will be applicable for every submission – even those of the same type.

There may also be relevant documents not included in the checklist because of the unique nature of a particular study or a reviewer's need for specific information on a particular study. It will be up to the investigator to determine if a particular document is applicable to their particular study. If you are unsure or need help deciding, contact us via chwirb@chw.org. This is available in IRBNet and on our Connect website.

Children's Logos, Templates, and Letterhead:
Note: Any use of the Children's Wisconsin logo must be approved in advance by Children's Marketing. Please contact kjohnson2@chw.org for review.

- Letterhead
- Logos
- Logos for email signature use
- PowerPoint Templates

Continues on next page.

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.

Investigator Sign-off in IRBNet

In addition to requiring Principal Investigator sign-off on ALL submissions, **starting May 1, 2021** we will require that any Investigator-level individuals being included or added to a study must also sign-off in IRBNet. Investigator sign-off will be required when:

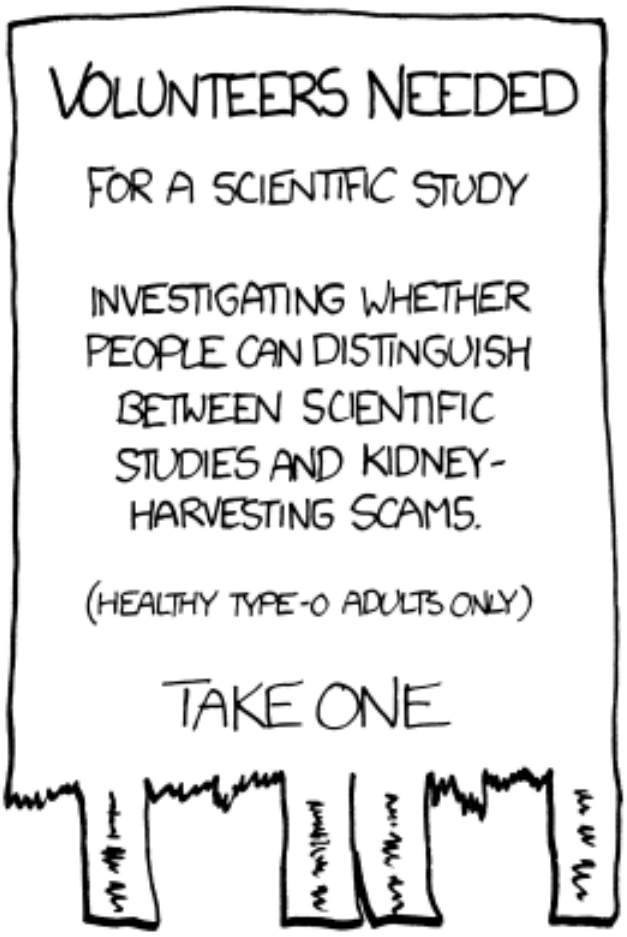
- The investigator is included as part of the study team in the initial submission; **OR**
- The investigator is added to the study in an amendment.

This sign-off ensures the HRPP/IRB that the investigator is aware of their role on a research project and that they are attesting that they will adhere to all investigator regulatory responsibilities.

Investigators (other than the PI) only need to sign the submission that adds them to the study (initially or at the time of an amendment) – they do not have to sign every submission as is required for a PI.

As with PI sign off, Investigator sign off can be accomplished by:

- Signing the package in IRBNet.
- Uploading a memo signed by the investigator indicating awareness of being added and accepting responsibility.
- An email, from the investigator's email account, indicating awareness of being added and accepting responsibility, uploaded into the submission.



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.

BEST PRACTICES

IRBNET REMINDERS

- PIs and study staff **must** review all IRB approval and decision letters. Federal regulations state, "An IRB shall notify investigators and the institution in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval of the research activity." Not only does the approval letter communicate to the PI all IRB determinations, but also actionable directives that require follow up.
    - When the approval letter indicates that there are items requiring follow-up, it is critical that the PI/study team complete the follow-up by the deadline indicated in the letter. HRPP staff will provide two courtesy reminders. If the modifications are not addressed by the indicated deadline, the PI must report the Noncompliance with an IRB directive (by submitting a reportable event package) and provide a detailed Corrective and Preventative Action Plan. Failure to follow directives in the approval letter may lead to IRB suspension of the protocol.
- A change in PI (either permanent or temporary) will require the submission of an amendment and IRB approval.
- Cover memos are not required to be included in a package, but should you choose to include one, be sure to explain all details (such as whether there are pending patients, active patients already enrolled, whether or not you have reached out to someone in the office to discuss submission details, etc.).
- If there is an amendment pending submission and the Continuing Review report has already been submitted or is due soon, you should reach out to the general office inbox (chwirb@chw.org). Occasionally other packages can be processed with or before continuing review submissions, but the HRPP office must be consulted first to discuss the most appropriate order of events and whether special handling is required.
- At the time of Continuing Review, if there have been no reportable events during the last year BUT updated Investigator's Brochures (new information package) have been submitted, you SHOULD include a Reportable Event/New Information log in the CR package to summarize the information for the IRB. This entry should indicate the date the package was initially submitted to the IRB. Also, please check the box on page 7 to indicate "This study has previously reported events" to alert reviewers to review the log.
- If the PI/study team wishes to communicate something to the HRPP/IRB staff, please utilize the main email chwirb@chw.org rather than including this in the comment fields in IRBNet. We can better manage these comments if they are sent to chwirb@chw.org.

TRACKING STUDY ENROLLMENT

EXPECTATIONS

It is expected that PIs and study teams develop a process by which screenings and enrollments to a research project are tracked. This is important in order to stay within the IRB approved enrollment number and avoid non-compliance as well as provide accurate reporting on enrollments at the time of continuing review.

When a project is submitted for IRB review and approval, the registration page asks for the anticipated number of subjects to be enrolled. The number provided is the number that the IRB approves, unless the committee specifically indicates otherwise in the approval letter (which you should be reading). The actual enrollments should not exceed this approved number. If you are reaching your approved enrollment goal but additional enrollments are planned, an amendment must be submitted and approved before adding additional subjects. The rationale for the change must be provided.

This is especially important for local single-site clinical trials and research projects that involve study interventions. As part of the review, the IRB assesses the statistical calculations for the number of subjects needed to ensure the aims of the study can be achieved and the research questions answered, weighing the risks of the study against the potential benefits. The least number of subjects possible should be exposed to the risks of the study. Although the considerations are slightly different for studies involving no more than minimal risk study, this is also applicable to chart review activities. We recommend you estimate on the high side to avoid having to amend the study frequently.

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 2 Dates
Thurs, May 6, 2021 @ 11:00 AM
Thurs, May 18, 2021 @ 2:00 PM

Thurs, June 3, 2021 @ 11:00 AM
Tues, June 15, 2021 @ 2:00 PM

Quarter 3 Dates
Thurs, July 8, 2021 @ 11:00 AM
Tues, July 20, 2021 @ 2:00 PM

Thurs, Aug 12, 2021 @ 11:00 AM
Tues, Aug 24, 2021 @ 2:00 PM

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

Continues on next page.

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 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!

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"

Pro Tip: Checklists

INFORMED CONSENT/PARENTAL PERMISSION/ASSENT

There is not a specific regulatory requirement that an informed consent checklist be used.

The regulations address what kinds are things are required in terms of consent (required elements of the document and process requirements such as: providing opportunity to consider participation without coercion or influence, that it is in a language understandable to the subject and does not waive or appear to waive the subject's legal rights or release investigator, sponsor, institution from liability, etc. (21 CFR 50.20; 21 CFR 50.25; 45 CFR 46.116 and 117). IRB review helps to ensure all required elements of informed consent are present; however, the ultimate responsibility for compliance rests with the principal investigator.

It is very important to recognize that informed consent is more than just a signature on a form. It's a process of information exchange that may involve recruitment materials, reading and signing the consent form, verbal instructions, measures of subject understanding, etc.

While not required per se by regulation, checklists and similar templates to document the consent/parental permission/assent discussion and how consent/parental permission/assent was obtained can be utilized to help ensure (and demonstrate on audit or monitoring) that investigators are complying with the regulations and helps prevent errors or inconsistencies in this process.

ROUND OF APPLAUSE

INSTITUTIONAL REVIEW BOARD: MANAGEMENT AND FUNCTION

The publication, *Institutional Review Board: Management and Function* is regarded as the primary resource for Human Subject Research/IRB professionals. This is a compilation of chapters on various subjects applicable to this work by leaders and experts in the field. The text was updated to the third edition this year and Lori Roesch, CIP, Research Integrity Manager was co-author of the chapter, "Activities That Are Not Human Subjects Research." Lori has many years of experience in Non-Human Subject Research determinations and we are very excited that she had the opportunity to share her expertise!

Additionally, several other HRPP staff members served as peer reviewers for other chapters in this new edition.

ATTENDING VIRTUAL IRB MEETINGS

MOVING FORWARD

IRB meetings will continue to be held remotely via the Zoom platform for the foreseeable future. As such, please be aware of some parameters to make this more efficient for everyone.

- Invitations will continue to be sent for the PI or study team to attend the meeting. Please confirm if someone from the study team WILL be attending. When accessing the meeting, guests are automatically admitted to the waiting room. If HRPP staff are aware of who will be attending, this makes it easier to note when they are in the waiting room and admit to the meeting at the appropriate time.
- Whenever possible, please use the Zoom app with your name, and not just initials or a series of numbers. Without this, or if we only see a phone number, we are not able to determine who is in the waiting room and for which study they should be admitted. To change your name after entering a Zoom meeting, click on the "Participants" button at the top of the Zoom window. Next, hover your mouse over your name in the "Participants" list on the right side of the Zoom window. Click, "Rename." Enter the name you'd like to appear in the Zoom meeting and click, "OK."
- Occasionally, when we send out convened IRB meeting invitations, we get requests for specifying what types of questions may come up from the committee. While we greatly appreciate efforts to come prepared to IRB meetings, and we do our best to catch/fix anything during pre-review that we can, ultimately we cannot predict questions the questions the Board may have.
    - Prior to IRB meetings, any member of the committee may reach out to the study team to ask questions, or there may be no specific questions. We indicate the reviewer(s) assigned in our communication to alert study teams about who is most likely to reach out. Most often, questions will relate to regulatory criteria for approval specific to the protocol being reviewed.

ADMINISTRATIVE UPDATES

NEW AND UPDATED RESOURCES

The HRPP 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 released and updated policies, guidance, and forms:

- New Guidance: Submissions of Investigator Brochures
- Updated Guidance: Reportable Information
- Updated Form: Continuing Review/Status Report/Closure Form
- Updated Form: Reportable Event Form
- Updated Form: Reportable Event Log

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