JULY 2021 | VOLUME 7 | ISSUE 3

HUMAN RESEARCH NEWSLETTER

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

IN THIS ISSUE

IRBNET UPDATE

USER REGISTRATION

IRBNet has updated the user registration process to enhance user security while providing a simplified registration experience for new users - a streamlined, single-step user registration process. As part of this enhanced process, all IRBNet users (including existing users) are prompted to maintain a recovery email address and recovery phone number to help ensure they are able to receive important security messages.

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!

EXPIRED STUDY SUPPLIES

REMINDERS FOR STUDY TEAMS

While research continues to ramp up since the start of COVID, please take some time to review all of your study specific supplies (tubes, kits, etc.) to ensure they are not expired. While using expired tubes may not necessarily harm the patient, it could affect the integrity of the study and patient satisfaction if a procedure needs to be completed a second time due to expired supplies. Using expired supplies should ultimately be avoided at all costs.

Also please remember that this is an institutional requirement. If a sponsor indicates that it is ok to use expired supplies, they must provide documentation and a plan for getting the supplies relabeled with a new expiration date. This plan will require prospective IRB review and approval via the amendment process.

Our hospital accreditation body expects that supplies in our clinical spaces are within their expiration date.

Please take the time to do the following for each of your studies:

1. Ensure an orderly inventory of your study supplies, ideally organized so that expiry dates are easily visible. Develop a plan to monitor when supplies are due to expire. Consider developing a tracking tool.
2. When you identify expired supplies, discard them per your sponsor's directions. If immediate discard is not possible, mark them to indicate they cannot be used.
3. If your sponsor recommends using expired supplies, they should work with the manufacturer to provide documentation of usability beyond the expiration date and a plan for relabeling.
4. Always check the expiration dates before delivering study supplies to clinical areas.

Unfortunately, if a study team delivers expired supplies to the TRU, TRU staff will not be able to use them.

We appreciate your partnership in this!

QUARTERLY EDUCATION

CHILDREN'S CAPA AND RCA PROCESS IN RESEARCH

Recently, HRPP and pTRU staff presented a quarterly education session on assessing Corrective and Preventable Action (CAPA) Plans and Root Cause Analyses (RCAs) when there is an instance of non-compliance. We have also updated our guidance on CAPA Plans. The recording will be posted to Children's Connect soon.

When available, you may access the recording here.

COMPLIANCE CORNER

USE OF CARE EVERYWHERE POLICY

There is a new Use of Care Everywhere policy now posted on Children's Connect: Privacy – Use of Children's Wisconsin Epic Care Everywhere for Research. As the policy indicates, if there are any questions regarding this policy or the use of Care Everywhere, please direct those to Diane Bauer, Research Compliance Manager.

CW does not yet have a secure texting platform in place, therefore, research teams cannot text appointment reminders or any communication to families/patients regardless how benign the message is and they definitely cannot be using their own cell phones to communicate with families/patients. What they can do is message the family/patient via MyChart. Diane Bauer can assist with specific questions regarding this for a study.

Families should not be asked to return signed research consents via MyChart because anything that the family/patient uploads into MyChart becomes a part of the legal medical record. Research consent forms are kept separate from the legal medical record when filed by HIM.

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 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.

ASK THE EXPERTS

ARTICLE FROM WIRB-WCG CENTERWATCH

WCG has a Q and A article related to IRB review and approval. This covers questions such as:

- What type of documentation or rationale may be needed to justify an Investigational New Drug (IND) exemption with an IRB?
- Can an IRB approve a trial before the FDA's review of the IND is complete?
- Is IRB review required when providing a link to ClinicalTrials.gov (CT.gov) postings on patient advocacy group websites and newsletters?
- Is IRB approval required before the links can be posted?
- If so, is central IRB review enough or, if an institution uses a local IRB, must it also approve?

***About CenterWatch**: They provide clinical trials information to professionals working at sponsors, CROs, research sites and niche service providers. Delivers insights every week through its newsletters, conferences, webinars, books, in-depth market surveys, industry profiles and clinical databases.*

FDA RESOURCES

REPLIES FROM FDA ON GOOD CLINICAL PRACTICE

This page is designed to simplify the search for copies of e-mail messages (including the original inquiry and associated reply(ies)) that have been submitted by the public to the Good Clinical Practice Program's gcp.questions@fda.hhs.gov e-mail account. The e-mail messages have been redacted to the extent permitted by the Freedom of Information Act and sorted into topic folders, which are updated on a continuing basis. The folders are prepared as self-extracting zip files that may be saved to your computer and opened, and the e-mail messages are saved in PDF format.

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.

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.

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.

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.

LIMITED ENGLISH PROFICIENCY

UNEXPECTED SUBJECT ENROLLMENT

Should the study team unexpectedly encounter a subject who has limited English proficiency, but meets all other study entry criteria, yet the study team does not have fully translated consent materials approved in the subject's native language already, one time use of the short form process may be permissible. The study team should prepare an amendment submission to the IRB for the study and minimally include an amendment form, the most recently approved consent materials (in English), the short form (in the subject's native language) with study information inserted in the appropriate sections, and a cover memo detailing the consent process (with use of an interpreter) including who signs which documents. Other items to consider are: does the study have questionnaires/surveys in the subject's native language (if not, is it appropriate to request a one-time protocol exception)? If the study is multi-center, does the coordinating center have any documents that are fully translated already which could be included for IRB review/approval? Be sure to email the main office email CHWIRB@chw.org to explain if this is a time-sensitive request or if you have any questions on how to prepare this type of package.

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 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

Quarter 4 Dates
Thurs, Oct 7, 2021 @ 11:00 AM
Tues, Oct 19, 2021 @ 2:00 PM

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

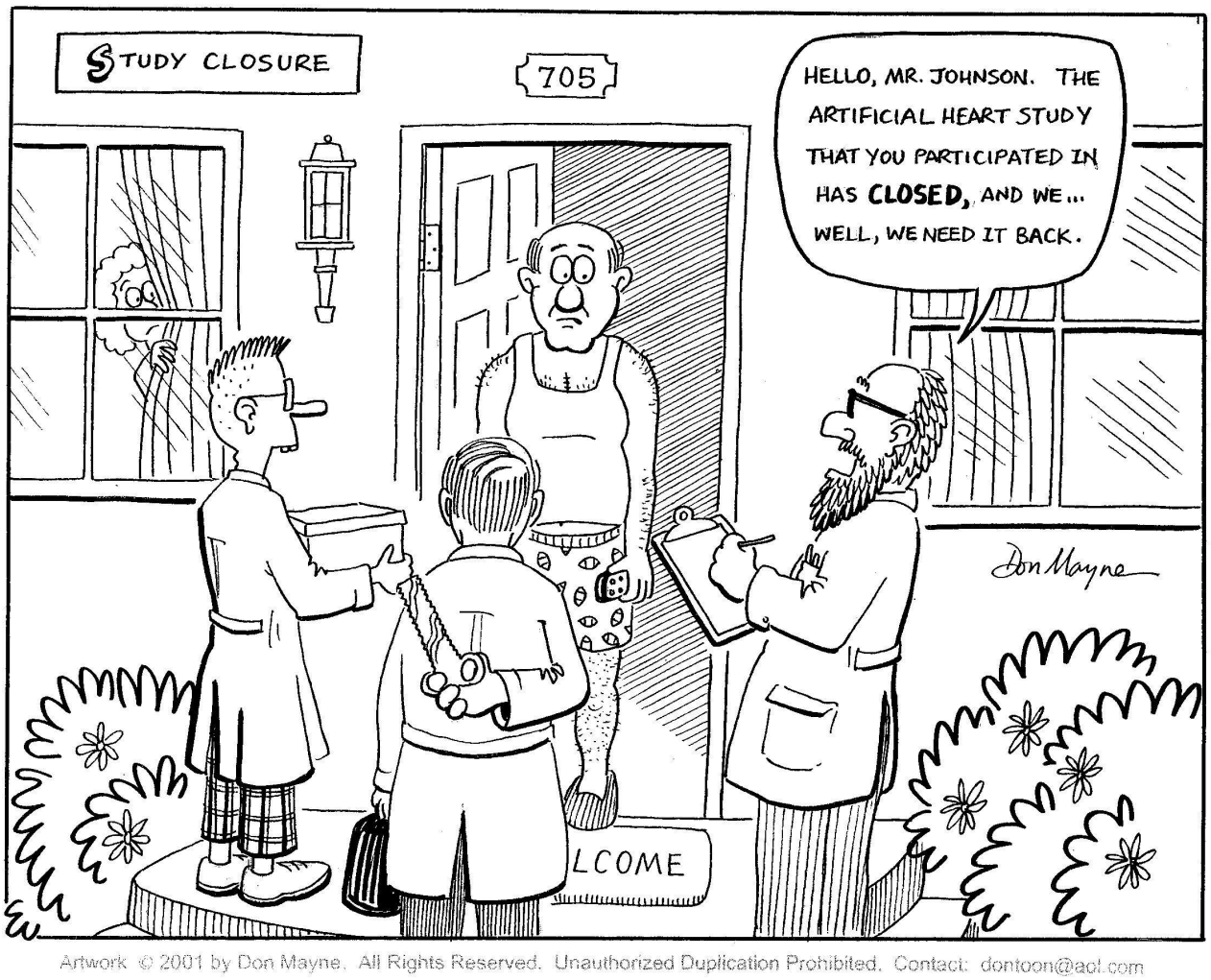
Introduction to the Children's Wisconsin IRB
This training session provides practical advice for working with the Children's HRPP Office to help ensure successful IRB submissions and ongoing (regulatory) study management. The goal of this program is to provide research staff – both coordinators and investigators – 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"



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:

- 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

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.