Human Research Newsletter

JULY 31, 2018 VOLUME 4, NUMBER 3

INSIDE THIS ISSUE:

Welcome New IRB Analyst Alexa Williams

I am a nurse with licenses in both Wisconsin and Florida. My husband and I moved our kids up from Florida almost two years ago. I have been a clinical research nurse for eight years now and have experience in many fields such as surgery, pulmonology, endocrinology, gastroenterology, obstetrics & gynecology, oncology, robotics, dermatology, and translational research.

I have experience with adults and pediatrics and have done drug, device, sponsored, and investigator initiated studies. I am currently attending UWM to advance my degree and hope to be done by next year. I also substitute teach ballet at the Milwaukee Ballet in Fox Point and have three children. My passion for research has led me on this career course and I am happy to be a part of the Children's Hospital IRB. I hope to bring my experience as a research nurse to my position as an analyst and provide exemplary work for my coworkers.

Common Rule 2018 (Final Rule) Update

There has been another delay to the general compliance date until January 21, 2019. Institutions are permitted (but not required) to implement three burden-reducing provisions during the delay period:

(1) The revised definition of "research," which deems certain activities not to be research;

(2) The allowance for no annual continuing review of certain categories of research; and

(3) The elimination of the requirement that institutional review boards review grant applications or other funding proposals related to the research

CHW does not have plans to implement these provisions before the general compliance date.

For more information see the OHRP memo dated June 18, 2018 (https://www.hhs.gov/ohrp/final-rule-delaying-general-compliance-revised-common-rule.html)

Research Study Stipends and Social Security Numbers (SSNs)

MCW recently provided a policy enhancement to the policy on collecting subject social security numbers when they receive a stipend for participating in research. **CHW will also follow this same policy.**

This update eliminates the need to collect an SSN from a research study participant receiving an individual gift card or cash payment of $60 or less. The removal of the SSN requirement only applies to gift card and cash stipends and not checks, which have historically generated IRS reportable income. The full policy, Business Purchases, Payments and Reimbursements, is currently available on InfoScope.

Notes to File – New IRB NTF

The IRB will be rolling out a new template (Note to File: Stamped Documents) that we would like you to be aware of. The intent of this is to provide a note for the study team research records if consent/HIPPAA documents are published without being stamped.

This should **not** be the norm, and we strive to be as thorough as possible. However, there have been instances when the IRB has mistakenly published documents without an approval stamp, or missed publishing a stamped document which was approved. While also not ideal, on occasion these unstamped documents have been used to consent subjects. In these cases we feel it is important to have a NTF for the research record to indicate that compliance regarding using a current, approved document was met, despite the lack of an approval stamp.

When we find this situation, we will post this NTF under board documents in the package to which is applies so that study teams can file this with the research records if needed.

As a reminder: before consenting a subject, **always** check the document you are about to use for a current IRB approval stamp. If there isn't one, look for this in board documents in the most recent package that approved consent forms. If it is not found, or an unstamped version is published **please alert the IRB office BEFORE using.** The IRB staff can correct this right away when we are notified. This will help avoid use of an unstamped document.

This template will be available in IRBNet and on the HRPP web pages in the very near future.

Did you know... in order to maintain hospital accreditation and compliance with the Joint Commission standards it is crucial that any skill performed on a Children's patient is only performed by Children's Hospital employees or providers who have competencies on file.

Who is considered a Children's Patient? A Children's patient is any person who is being seen for care at Children's hospital regardless if it is for clinical or research care.

What does this mean for my research? The Pediatric Translational Research Unit (TRU) is available to provide these patient care services or can direct you to appropriate personnel.

Appropriate Use of Notes to File in the Research Record

While we are on the topic of Notes to File, we wanted to provide some guidance on the appropriate use of NTF.

1. When should I use a NTF?

In general, NTFs are used in the following instances:

- To document the reason for missing, delayed or erroneous documents in the regulatory binder
- To explain protocol deviations or investigator site practices that are different from the norm or from what is prescribed in **the protocol.**

2. How should a NTF be prepared?

A Note to File should:

- Be generated on a case-by-case basis
- Include the subject and protocol it refers to (if it is subject related)
- Be signed and dated by the individual who is writing it
- Be legible if handwritten
- Explain clearly and *specifically* the reason for the error/omission/discrepancy or process/policy it aims to address.
- Should include any corrective action or follow-up when applicable.
- Be filed with the document, subject file or within the study binder to which it applies

3. To report or not to report?

Although NTFs are documented and filed in the regulatory binder/ subject binder, the event may still need to be reported to the IRB, the NTF does not fulfill the reporting requirement. For more information about reportable events, please review the "Guidance:Reportable New Information" found in IRBNet or on the HRPP web pages.

Reference:

Hazra, Aditi. "Use, Abuse and Misuse of Notes to File." *Perspectives in Clinical Research* 2.1 (2011): 38–40. *PMC*. Web. 16 July 2018.

IRB Committee Rosters Archived on Web

Past IRB Committee rosters are now posted on the HRPP landing page. Currently, these rosters go back a little more than a year to March 2017. Hopefully this will help with quick access to previous rosters when sponsors request them. If you need a roster going back further than is posted, please contact the IRB office and staff can send this to you.

PEDIATRIC TRU UPDATES

Welcome New TRU Staff!

The TRU has welcomed two new RNs to their team.

Sonia Pacheco joined the TRU on May 21st. She comes to the TRU with over 5 years of nursing experience with her most recent experience in our Children's Infusion Center.

Heidi Hoeppner re-joined Children's and the TRU on June 4th. She comes to TRU with nearly 20 years of nursing experience and about a year of GI Research experience at MCW from back in the late 90's.

Both RN's bring a wealth of great nursing experience and are eager to immerse themselves into our amazing research environment.

Save the Date!

Children's Research Institute and the Pediatric Translational Research Unit hope you can join us in celebrating all you contribute to research! We value each and every one of you!

When: Monday, September 24th 1:30-3pm
Where: Center 4 South – TRU Conference Room
Why: Because you are awesome!

Please join us in the Pediatric TRU for an ice cream cone or build your own sundae in honor of MCW Research Day – stop for a quick bite or stay for some networking time with other research teams.

We hope you can make it!
- Children's CRI Team (Elizabeth Bedwell, PTRU, IRB, and Grants & Contracts)

REGISTRATION PAGE UPDATE IN IRBNET

In the next few weeks you will see an update to the section in the registration page regarding use of the pediatric TRU. This section is only completed if you answer "yes" to the question about whether you will be using TRU resources. This section is now much more streamlined and reflects current information needed by the Pediatric TRU.

or more information and updates on education opportunities visit the HRPP webpage at: https://connect.chw.org/departments-services/clinical-departments/childrens-research-institute/human-research-protection/education-training

Children's Hospital of Wisconsin Human Research Protection Program/Institutional Review Board

Children's Corporate Center
999 North 92nd Street, Suite #120
Milwaukee, Wisconsin 53226

We're on the Web!

https://connect.chw.org/hrpp

Questions, Comments or Suggestions:

Your thoughts and recommendations for future newsletter items are much appreciated. Please send ideas and feedback to Michelle Martin, CCRP at MMartin@chw.org

UPDATES, REMINDERS AND TIPS

- **Study Closures:** once a study is closed with the CHW IRB, there are still a few other things that need to be addressed:
  - Complete your study and all enrolled patients in EPIC
  - Close out any EPIC specific orders that were built for your study (i.e. therapy plans, panels, order sets, etc.)
  - Alert the TRU Manager/TRU Research Coordinator if your study was run in the TRU or utilized the laboratory database
  - Alert Compliance of study close out for billing purposes.

- **Continuing Reviews**: The deadline for submitting annual continuing review to the CHW IRB is **60 days BEFORE** expiration. This is required to provide sufficient time for review and for any required modifications to be done before the expiration date. Particularly in cases where the convened board needs to review, we want these on the agenda the month prior to expiration to allow for any conditions of approval to be satisfied before the expiration date. If a submission comes in too close to the expiration date, there may not be time to either complete a review, or get it on an agenda, before the study lapses. There are several auto-notifications generated by IRBNet reminding PIs about the upcoming study expiration and the need for a CR report submission (these continue to generate until the study has a board action so if you know this has been submitted these reminders can be disregarded.) Please remember that Federal regulations indicate it is the PIs responsibility to keep track of expiration dates, CR submission dates, and to ensure that these are submitted in a timely manner. We continue to see many CRs submitted past this deadline. This causes undue and unfair "scrambling" for IRB analysts and primary reviewers to complete these before the project expires, which often requires stopping review of another investigator's project. In other cases, studies have expired because they were submitted late.

- **Amendments:** When submitting an amendment, please review the CHW summary form to determine if any updates are needed due to the changes being made with the AM. In many cases this document serves as the protocol, and it **always** represents the local context considerations (what will be done regarding the conduct of the study here.) In essence, the information contained in this document is what the IRB has approved regarding the conduct of the study. Therefore, this **updated** summary **must** be submitted with the AM package so the reviewers have access to, and are approving, the most up to date information regarding the conduct of the study at CHW.

Education Opportunities

Small Group Education Sessions-TRU and IRB Staff

Join IRB and TRU staff for informal presentations and small group discussions of select research topics. Space is limited, however, the same topic will be discussed at the two sessions each month. This will also be an open discussion and a chance to bring your questions or get assistance with EPIC or IRBNet.

These will meet in the TRU: **Center 4 South, Main Hospital**

Upcoming sessions:

08/07/2018 @ 2:00pm	Use and Abuse of Notes to File
08/23/2018 @ 10:00am	Use and Abuse of Notes to File
09/04/2018 @ 2:00pm	Expanded Access – Individual Patients
09/20/2018 @ 10:00am	Expanded Access – Individual Patients

CRI Quarterly Education Session – Oct 23, 2018
The topic for this session is "2018 EPIC Upgrade Review and EPIC Research Study Maintenance."

Please forward your questions or concerns to Jeff Crawford at JCrawford@chw.org in preparation for the session on Oct 23rd .

This will be held in the Children's Hospital Auditorium from 8:30am to 9:45am.

IRBNet Document Library and Website Updates

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

Forms posted:

- Past IRB Committee Rosters