Human Research Newsletter

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INSIDE THIS ISSUE:

Use of Imaging in Research Studies – Follow Up

Last issue we mentioned a form is being developed by the Department of Imaging which will need to be completed and provided to Linda Strain (Diagnostic Nurse Manager) for review. This form, *Imaging Research Intake Form*, has been finalized by Linda Strain and is posted in IRBNet and on the HRPP web pages.

As a reminder:

- If imaging is being done solely for research purposes the research must first be reviewed by the appropriate safety committee.
- Even if all imaging being done as part of the research study is considered standard of care, if the imaging will be done at CHW/with CHW equipment as part of a research study (it is described in the protocol), the CHW Department of Imaging needs to be notified/consulted prior to submitting the study to the IRB.
- When the research study (or amendment adding imaging) is submitted to the IRB it should include either documentation from Linda that the imaging department is aware of and can support the study, or a sign-off of the package in IRBNet from Linda.

CHW IRB Open Office Hours Update

Open Office Hours continues to be utilized on a regular basis. As such, we have added an additional day. Office hours are available:

- Tuesdays 9:30am – 11:30pm
- Fridays 1:30pm – 3:30pm

As a reminder, the intent is for members of the research community to be able to drop in for quick questions and guidance about project. If you need to discuss a complex study/issue or anticipate needing more than 15 minutes please utilize the IRB consultation request process by completing and submitting a consultation request form. Our main phone line (414-377-7133) and general email (chwirb@chw.org) are also available.

July	14
August	7
September	9
October (so far)	5
Total	**35 Participants**

IRBNet Auto-Reminders for Continuing Review Updated

Based on feedback from the research community, the IRBNet generated automatic reminders to submit continuing review (CR) report have been updated. The change is within the subject line which now references days until the CR submission is **DUE**, rather than days until project expiration. Project expiration date will remain in the body of the email. Hopefully this will help alert research teams to the approaching **submission deadline** (60 days BEFORE project expiration date).

The reminders will still go out at the following intervals:

- **90 days before expiration** – the subject line will indicate that at this point there are **30 days** until the CR submission to the IRB is due.
- **60 days before expiration**- the subject line will indicate that at this point the CR submission to the IRB is **due TODAY**.
- **30 days before expiration** - the subject line will indicate that at this point the CR submission to the IRB is **PAST due**.

As a reminder, these notifications are automatically generated by the IRBNet system. You will continue to get reminders even after the CR has been submitted – the first line in the body of the message instructs reader to disregard if the CR has already been submitted.

Updated Institutional Form for Reliance Agreements/Deferrals

We have updated our Children's Institutional Form. This was done to help increase our efficiency in processing reliance requests and hopefully cut down on the number of back and forth emails we need to have between IRBs and study teams.

Previously, a version of this form was an addendum to the existing Investigator Reliance Request Form and it will continue to be an addendum. However, we will now require it be filled out for ANY study involving Children's data, patients, or spaces.

We will be publishing the newest version on our HRPP website as well as in IRBNet by November 5, 2019. Any new requests after this form is available will need to include this and if missing, study teams will be asked to submit it as part of the completeness check process.

As a reminder, we also now have an email template, which can be utilized to help cut down on the number of questions as well. It can be found on our website (scroll to "Reliance Requests").

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.

Spotlight on the IRB Members

IRB Chair of Committee #2: Dr. Louella Amos

Briefly describe your professional background & career

I'm a pediatric pulmonologist and sleep medicine specialist. I am a Wisconsin Badger who received my undergraduate degree and MD at UW Madison. Then I went all the way back to Milwaukee which is where I'm originally from and completed pediatric residency, Pediatric Pulmonary fellowship and Sleep Medicine fellowship. I feel like I am an offspring of CHW.

Tell us what motivated you to become an IRB member

There were many CF research protocols being submitted to the IRB, so my section chief and Paul Scott felt that it would be a good idea to have Pulmonary representation on the IRB. I was a bit nervous about taking this role on, but I have learned a lot about the amazing research going on in our institution, and it has helped me be a better researcher myself.

What is your favorite personal time activity?

I love playing tennis, competitively and for fun. However I didn't always love it. I played tennis all the time as a junior (in grade school and high school) and burned out. Once I went to college I swore I would never pick up a racquet again. Now, it is my fitness and mental health. It's a social outlet for me, it helps me sleep and I'm a happier person.

Communications from the HRPP/IRB Office

We want to remind all study teams that PIs and those delegated to carry out study related activities and manage research protocols have

a responsibility to carefully and thoroughly read all communications sent through IRBNet or from the HRPP/IRB office. This includes:

- Auto-notifications generated by IRBNet (board actions, board documents published, reminder to submit CR, etc.)
- Project mail sent via IRBNet
- Unlock messages and Pre-review memos
- Decision letters
- Email from reviewers, analysts or other HRPP staff sent outside of IRBNet.

REGULATORY REQUIREMENT – Each IRB must follow written procedures for conducting initial and continuing review of research and for reporting IRB findings and actions to the investigator and the institution [45 CFR 46.103(b)(4)(i), 21 CFR 56.108(a)(1)]

Communicating the IRB's findings and actions to both the investigator and the institution, include:

- Communicating to the investigator any modifications or clarifications required by the IRB as a condition of approval.
- Reviewing and acting on the investigator's response to any required modifications or clarifications required by the IRB as a condition of approval.
- Communicating the reason(s) for a decision to disapprove, and the process followed to allow the investigator to respond.

CHW IRB's findings and actions are made available via IRBNet, which serves as the official repository for all communication. It is reviewed by regulators in the event of an audit.

When an investigator does not read IRB correspondence, that would be considered a failure to follow federal regulations and can have unintended consequences.

PEDIATRIC TRU UPDATES

EPIC Reminder: Jeff Crawford is your Research Epic Credential Trainer. If you ever have any research related questions, comments, or concerns please contact Jeff – jcrawford@chw.org or 414-266-7254

Transition to Epic's Storyboard view underway

As of Sept. 23, all Children's clinical users have Storyboard view for patient information in Epic. In this new view, the patient header across the top will move to the left side of the patient chart. The activity tabs found along the left side of the chart will appear across the top.

Key things to know during the Storyboard transition period:

- The Storyboard tip sheet, found in your Epic Learning Home, includes tips and instructions on switching between Storyboard and the patient header view.
- Storyboard only affects the look of Epic when you are in a patient chart.

Storyboard view should now be on for everyone. Users are no longer be able to switch Storyboard view off.

Call Jeff Crawford @ (414) 266-7254 with any questions.

Education Opportunities

CRI Quarterly Education Session

Robert Niebler, MD from Critical Care Services will be providing a presentation titled "Clinical Research and the FDA: "Compassion," Emergencies and your very own IND".

October 22nd, 2019; 9:00am – 10:30am; CHW Auditorium

Small Group Education Sessions-with TRU and IRB Staff

Join IRB and TRU staff for informal presentations and small group discussions of select research topics. 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 conference room: Center 4 South, Main Hospital

October 24th, 2019 @ 10:00am
November 14th, 2019 @ 10:00am
December 10th, 2019 @ 2:00pm

Introduction to the CHW IRB –Monthly Education Sessions

Starting in 2020, the CHW HRPP/IRB will be offering a monthly session to introduce the CHW IRB to those who are new to working with us. The session is designed to provide **introductory** information specifically about the CHW IRB/HRPP, our review process, resources available, and how to navigate and use the IRBNet system to submit to the CHW IRB.

The intended audience for these 4 hour sessions is anyone who is or will be new to working with/interacting with the CHW IRB or submitting/maintaining projects in IRBNet (our electronic submission system). Current team members can provide this as learning opportunity for onboarding any new team members in your area.

This will be information that is very specific to working with the CHW IRB , rather than broad information about IRBs and Human Research Protections or conducting human subject research (which is information covered in other venues such as the CITI training modules.)

Watch for the upcoming schedule on the Connect HRPP Webpages and future newsletters. There will be a registration process via the HRPP webpages to sign up for a particular date.

Research Ambassadors Update

MCW has recently developed an institutional policy for Clinicaltrials.gov Registration and Compliance.

https://infoscope.mcw.edu/Corporate-Policies/ClinicalTrials.gov-Compliance.htm

In addition, a shared process has been developed to support MCW research stakeholders and to improve institutional compliance. The Office

of Research will be responsible for CT.gov compliance monitoring and escalation. The CTSI will establish a training program and will support end users as the CT.gov Helpdesk.

Departments have identified Subject Matter Experts to assist the Office of Research and CTSI with registration and compliance across the institution.

The Subject Matter Expert for the Department of Pediatrics is Christine Long: clong@mcw.edu

Kathy Murkowski kmurkows@mcw.edu and Theresa Kump tkump@mcw.edu will also be available to assist investigators in the DOP.

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/guidance/web pages recently posted:

- **New** Policy added to IRBNet and the Website: Appeal of IRB Decisions
- **New** Policy added to IRBNet and the Website: Closure of Research Study with the CHW IRB
- **New** Guidance added to IRBNet and the Website: IRB Review Process Flow Chart
- **New** Guidance added to IRBNet and the Website: Conducting Investigator Initiated Multi-Center Collaborative Research Activities

Ambassadors serving the Pediatric / CHW research community are:

Theresa Kump
Department of Pediatrics
tkump@mcw.edu
414-337-7144

Nicholas Peterson
Department of Surgery / Herma Heart Institute
npeterson@chw.org
414-266-1753

Ed Bedjeti
Urology: Pediatric Urology / Pediatric Surgery
ebedjeti@chw.org
414-337-3441

For more information and updates on education opportunities visit the HRPP webpages

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, CIP at MMartin@chw.org