Children's Hospital of Wisconsin

Human Research Newsletter

AUGUST 31, 2016 VOLUME 2, NUMBER 3

INSIDE THIS ISSUE:

Managing Documents in Continuing Review Submissions

Last issue we provided instructions for a new process to manage documents in IRBNet submissions – attaching as new documents versus revisions to previously uploaded documents. This issue provides further clarification on how to manage documents for continuing review submissions.

Currently the IRB is requesting study teams continue, for the time being, to upload clean versions of study documents with the continuing review submission for stamping. Because this is a continuing review, these documents are neither new, nor revisions, which leads to questions about how to attach these for a continuing review.

Teams should upload the most current, clean version of the documents as a **revision** to that document in IRBNet. There will NOT be a tracked version to upload – just upload the current clean version using the revision function. Please do this rather than attaching the current clean versions as new documents. If there have been previous continuing reviews, the continuing review form should also be uploaded as a revision to the previous CR form. If this is the first continuing review, upload the form as a new document. If teams continue to upload these as new when previous versions already exist in IRBNet, this adds to the list of documents, rather than establishing a continuous document revision history as per the new process for managing documents.

For further information, please refer back to the guide sheet on Managing Documents in IRBNet. If you have questions, please contact the IRB staff.

Sign Offs in IRBNet

The Amendment form was updated in June of 2016. One of the changes was the addition of section #8 regarding ancillary services that may be involved with the project and whether these areas have been notified.

As a reminder, when there are ancillary hospital services that may be involved with research procedures for a project, staff in that area need to be aware of the study and what is involved. Examples include: pharmacy, laboratory, Pediatric TRU, imaging services, etc. Leaders in the affected area must be provided with the protocol and study information for reference and have a chance to review the impact this may have on the respective area. This should be done via their sign off on the project in IRBNet – when it is submitted as a new project and when

there are any changes to the protocol and procedures that affect their service area.

Be sure to share projects with the personnel responsible for these reviews in the applicable areas, and send them a reminder to log into IRBNet to review and sign off when you have submitted an applicable package (new study or amendment.) Please contact IRB staff if you have questions about how to share a project. Contact the specific area to determine who the appropriate personnel is to review and sign off on a project.

Research Support from the Pediatric TRU

Are you or your study team in need for research support regarding:

- Epic Training Resources
- General Epic Navigation
    - (i.e. Study Creation, use of the charge notification form, Chart Navigation, etc)
- Budget consultation or assistance with budget negotiation

If so, please feel free to reach out to Jeff Crawford directly via telephone (414-266-7254) or email (jcrawford@chw.org)

New: Human Research Protection Program Web Pages

The Human Research Protection Program has new web pages on both Children's Connect and CHW.org. This is the beginning of what we hope will become a "go to" resource for information about human subject research at CHW and human subject protection. We have a starting structure up, however, not all links are active yet, and content is still being added. This will continue to evolve as we add and update content.

Please forward any suggestions for content, feedback, questions, etc to the IRB staff so we can make this as useful as possible for the CHW research community. There is a "give us your feedback" form via the web pages, or you can email directly MMartin@chw.org.

On Connect Intranet (only accessible via CHW log in): https://connect.chw.org/departments-services/clinical-departments/childrens-research-institute/human-research-protection

On CHW.org (publically available): http://www.chw.org/medical-professionals/research/human-research-protection-program/

Education Opportunities

Achieving Excellence in Clinical Research: Scientific, Ethical and Operational Considerations

Friday, September 30, 2016 – McDonald's Hamburger University – Oak Brook, Illinois.

Topics include:

- Levering Big Data for Clinical Research
- How Do You Know What You Think You Know?
- The Changing Landscape of Human Subjects Research
- Building Successful Academic, Corporate and Clinical Partnerships to Advance Your Research
- Using Big Data to Evaluate Clinician-Sensitive Outcomes
- Beyond Protocol Deviations: Therapeutic Misconception and the Clinician-Researcher
- Research Literacy: Strategies to Foster Comprehension with Study Subjects
- Clinical Research in Pregnant Women: Process, Promise and Perils
- Keeping the Spark Alive During Long-Term, Multi-Center Trials

This is geared toward an audience of Physicians, Nurses, IRB Members and other professionals involved or interested in clinical research.

A brochure and registration is available on their website at http://www.advocatechildrenshospital.com/ach-annual-conference. For more information call 847-723-2164.

Quarterly Education Session: Research Operations and Resources

September 13, 2016 10-11:30am – Children's Auditorium

Objectives:

- Ability to navigate through the numerous CHW and MCW resources
- Identifying key contacts on campus to assist with research operations (i.e. finance, compliance, professional fees, etc)
- Brief update of impact for November 12, 2016 EPIC upgrade

10-11am is content presentation

11-11:30am questions – if you have a specific question beforehand, please submit to jcrawford@chw.org and we will do our best to address it.

Questions? Please contact Jeff Crawford – Pediatric TRU CRC 414-266-7254

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

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We're on the Web!

http://www.chw.org/medical-professionals/research/human-research-protection-program/

https://connect.chw.org/departments-services/clinical-departments/childrens-research-institute/human-research-protection

Pediatric Translational Research Unit

September Research Networking

Thursday September 8th 2-3pm in the Pediatric TRU

Join us for our Bi-Monthly Research Support Staff Networking session in the Pediatric TRU!

TAKE A BREAK to get to know other CRCs and Research Assistants from other departments/divisions

We hope you can make it!
Snacks provided by the Pediatric TRU Team

Happy MCW Research Day!

Wednesday, September 21, 2016.

Please make a quick pit stop by the Pediatric TRU (located behind the welcome desk on Center 2) for a treat in honor of all that you do as a researcher at MCW/CHW. If you haven't been here before, we'd love to offer you a quick tour of our department.

IRBNet Document Library

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

Updated Forms and Documents:

- Amendment Form (revised)
- Continuing Review Form (revised)
- Consent template for Single Patient IND **(new)**
- Policy – Reportable Events (revised)

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