Children's Hospital of Wisconsin

Human Research Newsletter

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INSIDE THIS ISSUE:

Finding and Using the Correct Informed Consent Document

Obtaining appropriate and valid informed consent from research subjects is a core ethical principle (respect for persons) and one of the most important ways that we protect human subjects. This cannot happen if investigators are providing subjects with unapproved or out of date versions of the consent document and calls into question the entire consent process.

Some potential issues that can arise when consenting subjects:

- Using an expired version
- Using an unapproved version
- Using an unstamped version of the approved form
- Using unstamped versions of expired forms

Federal regulations state "***no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative***." (*45 CFR 46.116*) (21 CFR 50.20). The regulations also stipulate that the process of how informed consent will be obtained, and the document that will be used, must be approved by the IRB. (21 CFR 50.27; 21 CFR 56.111; 45 CFR 46.117; 45 CFR 46.111)

CHW IRB policy requires that "*only the most recent IRB approved informed consent form may be used to obtain consent from prospective subjects*" and "*any changes or revisions to an approved version of the informed consent must be IRB approved prior to use.*"

The current IRB approval stamp on the signed consent signifies that an approved, current version was used to enroll a particular subject.

Problems that arise from using the incorrect consent form:

- Subject may receive incorrect or out of date information and are not fully informed about the most current information available about the research study

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.

- Presents a violation of federal regulations and CHW policy
- Use of a document with approved language, but without the IRB approval stamp, creates difficulty in verifying whether the current, approved form was used
- Significant time on the part of the HRPP staff, IRB members, and study team is spent investigating the chain of events that occurred with these reportable events (conducting a root-cause analysis, creating and submitting a report, reviewing and getting additional information, creating an appropriate corrective and preventative action plan, etc.)

When consenting subjects to a study, they **MUST** be provided with the current, approved, and stamped version of the consent form (unless the IRB has granted a waiver of parental permission/consent or a waiver of documentation of parental permission/consent.)

When consent documents are part of the submission, approved and stamped documents are published in IRBNet when the determination/approval letters are published. The IRB also publishes clean word versions of the currently approved consent document. However, these versions are intended as a convenience for the study teams, to provide an up to date document from which to base the next set of modifications. This unstamped version should **NOT** be provided to subjects.

Ways to avoid using an incorrect consent document:

- Obtain the most current, approved, stamped document from IRBNet.
  - We **STRONGLY** discourage pre-printing a supply of consents after IRB approval and having these distributed in various places.
  - While we appreciate that study teams may have their own systems of storing documents on computers or in shared folders, there is a lot of room for error with this method (and we have seen all of them!)
- Ensure that ALL members of the study teams responsible for providing the consent documents to subjects (or to whomever will be consenting) are trained and familiar with how to find these documents in IRBNet. This includes Principle Investigators. It is particularly important to be sure that new study team members are aware of how to used IRBNet and find these documents.
  - Contact Michelle Martin in the IRB office at 414-266-7474 or mmartin@chw.org if you would like some in person instruction for your team regarding this
  - Utilize the IRBNet instructional resources available on the HRRP web pages (Resources and Guidance for Researchers) for information on using IRBNet and locating documents.

- Get in the habit as part of your enrollment process of checking the consent document for the IRB approval stamp. This step could be incorporated as part of an enrollment checklist.
  - If there is no approval stamp you have the wrong document
  - If the approval stamp indicates an expiration date that is PRIOR to the date you are consenting, you have the wrong document.
- Perform periodic self-audits of the study's consent forms to determine if there is a problem and/or to monitor the process in place for ensuring that correct forms are used
- Create a process for ensuring that current, stamped documents are used

In the event that a reportable event **is** needed to alert the IRB that an incorrect consent form is used, be sure to provide the IRB with adequate information to help the board determine appropriate action/follow-up and to prevent the need for a lot of follow-up questions.

This should include:

- What the problem was (use of a stamped but expired form, versus used of an unapproved form versus use of an unstamped form)
- How many subjects were affected
- How the error was discovered
- When the error was discovered
- How it was verified whether the form used for ALL affected subjects contained the most current information
- What was the corrective action taken (were subjects re-consented on the correct form? If not why not? Were there other corrective actions taken to ensure that the subject was fully informed, etc.)
- Describe the current process for obtaining consent documents to be used when there is a potential subject and study team members responsible
- Describe changes to be made to that process as part of the preventative action plan to avoid future mistakes. If study team training and education is part of the preventative action plan, describe fully what that training involves (by whom, with whom, information to be presented and how)
- Describe how the proposed preventative action plan will be monitored once implemented to be sure that it is working

Office for Human Research Protections (OHRP) Educational Video

General Informed Consent Requirements (18:38)

This dramatization starts with a fictional investigator and IRB Chair talking about obtaining legally effective informed consent from potential research subjects. The second scene portrays the investigator obtaining appropriate informed consent from a potential subject. (Aug 24, 2010)

Watch: General Informed Consent Requirements

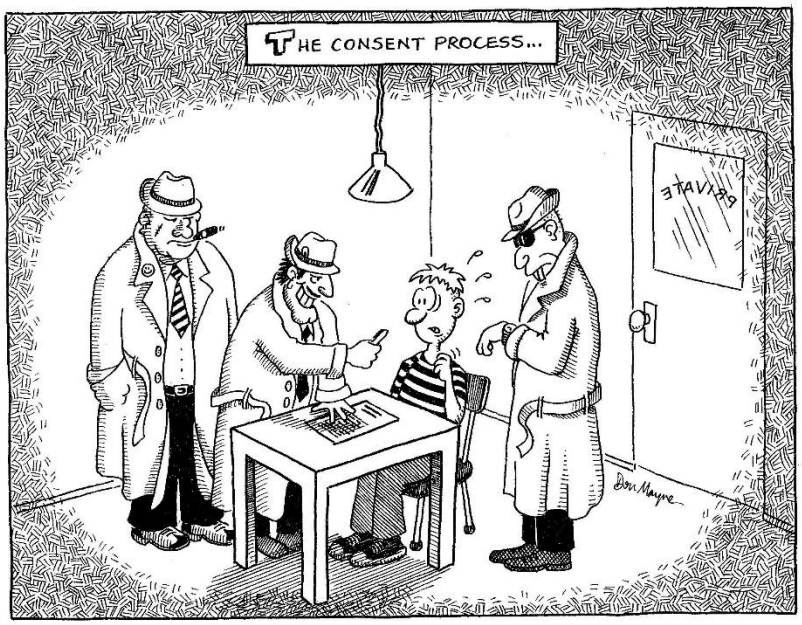
Article: Scientists And Parents Band Together to Research Cures for Rare Childhood Cancer

"In 2016 the Creating Hope Act introduced incentives for industry to invest in rare childhood diseases. But pediatric cancers offer little payoff for the investment in drug development compared to breast or colon cancer, for example, where patient numbers reach "hundreds of thousands, rather than hundreds," says Jim Geller, an oncologist at Cincinnati Children's Hospital."

"Because there are so few cases, "trials cannot be conducted quickly, nor can you conduct multiple trials on the same disease as easily as in adult cancer," he says. And so very few new treatments are in the pipeline. This means families can find themselves out of options very quickly when their kids get sick."

"The Children's Cancer Therapy Development Institute, just outside of Portland, Ore., takes a more coordinated approach, one that is channeling families' desperation to quietly transform pediatric cancer research. In less than three years after the Institute began operating out of a remodeled paint factory in Beaverton, Ore., it has pushed new drug candidates into three clinical trials."

National Public Radio
October 26, 2018



Does Your Study Involve Froedtert Hospital Resources or Subjects?

If so, you probably already have or will be asked to contact the Office of Clinical Research and Innovative Care Compliance (OCRICC) at some point to seek Froedtert Health administrative approval. In order for OCRICC to have the ability to grant this approval, their staff needs read access to study documents in IRBNet. Previously, research teams had to ask the CHW IRB office to add certain OCRICC staff members individually, sometimes multiple times throughout the life of the project, which was not efficient for anyone involved. This process changed a short time ago. If you have an existing project involving Froedtert, if you know your new project will involve Froedtert, or if you are amending your existing project to add Froedtert, please 'share' the project with the following individuals from OCRICC: Roberta Navarro, Joanna Delap, Elizabeth Polak, Leslie Manion, Janelle Byrum, Sarah Holze, and Jennifer Martone and provide 'read' access. (Same way you share projects with pTRU or pharmacy.) This will enable the OCRICC team to review necessary documents as time allows. If you are unsure of whether your project requires OCRICC review, please contact OCRICC to find out (ocricc@froedterthealth.org).

PEDIATRIC TRU UPDATES

EPIC Upgrade 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

Research Coordinators and Assistants:

- Don't forget to visit your EPIC learning home for the most up to date Tips & Tricks.
- Slides from the Research EPIC Upgrade session will be posted by the end of the week to the training/education HRPP website.
- Also – Save the Date: Post Thanksgiving Networking session!

UPDATES, REMINDERS AND TIPS

- **From Corporate Compliance:** When individuals leave CHW, **NO** PHI is to be taken out of CHW. If you require guidance on this when a study team member is leaving, or have further questions, please contact Diane Bauer in Corporate Compliance at dbauer@chw.org.

- **Keep IRBNet access up to date.** When amending a study to remove study staff from the project, remember to also change their status in IRBNet to "no access" for that project through the "share this project" link/button in IRBNet.

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

- **Unauthorized release of PHI**: If your study has a problem regarding an unauthorized release of PHI, the PI should **NOT** send any communications about this directly to the study subjects affected. This should be reported to the IRB as a reportable event/unanticipated problem. The event will be assessed by corporate compliance and any communications to subjects about this must come directly from compliance.

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:
11/06/2018 @ 2:00pm - EPIC Upgrade and Research Maintenance
12/04/2018 @ 2:00pm - Using IRBNet More Effectively
12/20/2018 @ 10:00am – Using IRBNet More Effectively

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 recently posted:

- Position Statement: Pregnant Subjects and Pregnant Partners of Subjects
- Registration page updated – Section on using the pTRU
- IRBNet tutorials and resources have been posted on the HRPP webpages

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

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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, CCRP at MMartin@chw.org