Children's Hospital of Wisconsin

Human Research Newsletter

OCTOBER 31, 2016 VOLUME 2, NUMBER 4

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Welcome New IRB Office Staff!

Angela Navarrete-Opazo, MD, PhD recently joined the CHW IRB Office as an IRB Coordinator. Angela comes to us from Teleton Children Rehabilitation Institute in Chile where she practiced as a Physical Medicine and Rehabilitation physician and worked with the Teleton Children Rehabilitation Institute IRB. She has been active in conducting pediatric human research and has a PhD in Neuroscience from UW-Madison, diploma in clinical research from the University of Chile, and is a Certified Clinical Research Associate. Angela brings diverse knowledge and experience in pediatric human subject protection and we are very excited to have her join our team. Please join me in welcoming Angela to the IRB office!

New Translated Short Form Consents Available

We recently had the short form consent translated into the following languages:

- Albanian
- Arabic
- Hindi
- Hmong
- Lao
- Polish
- Russian
- Serbian

We continue to have the Spanish translated short form available as well.

In addition, the boilerplate consent language used for the Children's Oncology Group studies deferred to the NCI CIRB has also been translated into Spanish. This allows for use of the COG provided Spanish translated consents, when available, with the addition of our local language.

Reminder: there are specific procedures for obtaining the

For more information see the HRRP Web Pages –

Resources and Guidance for Researchers

consent of non-English speaking subjects and for implementing the use of the short form consent as an option for documenting their consent. The short form consent must not be used without prior IRB approval, which is granted via an amendment when an unexpected non-English speaking subject is encountered. The policy and the short form templates are available for download on the HRPP Resources and Guidance for Researchers web page.

Obtaining Consent v. Documenting Consent

Did you know there is a difference between obtaining informed consent and documenting informed consent?

Obtaining consent is the process by which information about research is presented to a subject, or their Legally Authorized Representative, and they voluntarily agree to participate. It is ongoing and much more than the subject signing a consent form. Obtaining consent is a discussion, with questions and answers, covering all the required elements of informed consent, in a way the subject can understand. This involves checking for subject's comprehension about the research and confirming their agreement, at the initial discussion and regularly throughout their participation. If a study changes, investigators should be discussing this with subjects, and checking for their continued consent to continue to participate as well as their understanding of the changes to the study.

Documenting consent, on the other hand, is the act of the subject, or their Legally Authorized Representative, signing the IRB approved consent form. This form is typically used as the basis for the discussion to obtain consent and is the summary of research provided to the subject.

The distinction is important, particularly when a waiver is requested. The IRB has the authority to waive the requirement to obtain informed consent, to approve the elimination or alteration of one or more of the required elements of informed consent, or waive the requirement for consent to be documented (waiver of signature). If a waiver of documentation of informed consent is granted, there is still the requirement to obtain consent, and the IRB may require a written summary of the study be provided to the subject. If a waiver of consent is granted then study activities can proceed without a subject's consent and thus there is no need to get a signature on a consent form, and no need to request a waiver for documentation of consent. Study teams should be requesting whichever is most appropriate, but not both a waiver of consent and a waiver of documentation of consent. Any waiver must meet specific criteria before the IRB will grant and the rationale for the waiver, how the criteria are met, should be explained to the IRB when requesting.

NOTE: FDA regulated research is not eligible for waivers of consent except in cases of emergency use or planned emergency

Obtaining Consent Regulations
45 CFR 46. 116
21 CFR 50.25.

Documenting Consent Regulations
45 CFR 46.117
21 CFR 50.27

Waiver of Consent Regulations
45 CFR 46.116 (c)
45 CFR 46.117(c)
21 CFR 56.109

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For reference:
CHHS CyberSecurity Policies and Standards Handbook
(access via Children's Connect Intranet if on an MCW computer)
MCW Corporate Policy and Procedures Information Technology: Information Systems Access
(access via MCW infoscope intranet)

use and many specific criteria must be met in these circumstances.

IMPORTANT REMINDERS

- When submitting a response package through IRBNet, please include a reference to which previous package you are responding. This can be done in a brief cover memo included in the submission.
- It is a violation of both CHW and MCW policy to share you login credentials or use another person's login credentials. This includes login to the IRBNet submission system. Users should only use their own, unique login credentials for any access to IRBNet. Users should never login as another study staff team member to submit or sign off on packages or for any other purpose. If you need to obtain a unique ID and password this can be done from the landing page of IRBNet at www.irbnet.org If you have questions about how to do this please contact the IRB staff.
- If you have new staff in your department that will be using IRBNet, working on submissions to the IRB, have them contact Michelle Martin at mmartin@chw.org to set up time for an orientation to the CHW IRB and training on how to use IRBNet.

Education Opportunities

Quarterly Education Session – December 13th, 2016
What questions do you have about Research Compliance and the HIPAA Privacy Rule?

Please forward your questions or concerns to Jeff Crawford at JCrawford@chw.org in preparation for the December 13th Quarterly education Session

This will be held in the Children's Hospital Auditorium from 10:00am to 11:30am.

New Lecture Series on OHRP Website

The Division of Education and Development has launched its new Luminaries Lecture Series, featuring talks by esteemed individuals with thought-provoking insights on human subjects research protections. The series is intended to be of broad interest to investigators and IRB professionals, as well as anyone involved in human subjects research.

Some of the featured lectures include:

- Dr. Celia Fisher on "Ethics and Social Justice in Health Research Involving Vulnerable Adolescents" and
- Dr. Richard Gorman considering the question "How Do You Know What You Think You Know?"

To view the current Luminaries Lecture available, visit: http://www.hhs.gov/ohrp/education-and-outreach/luminaries-lecture-series/index.html

Educational Workshop in Chicago, IL
OHRP is collaborating with the NIH Office of Extramural Research to host an educational workshop on "Getting Through Human Research Reviews with Skill," October 26, 2017 in Chicago, Illinois. This workshop is designed for early-stage investigators, but would also be a good basic training or refresher course on the federal policies for new IRB administrators or reviewers.

For more information and to register go to:

http://event.capconcorp.com/form/view.php?id=15795

Pediatric TRU Updates

Interested in the EPIC 2015 upgrade?

Find out what this may mean for your Research workflow by visiting the 'Research Tools and Education' link at https://connect.chw.org/TRU

IRBNet Document Library and Website Updates

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.

Website content added or updated:

- Informed Consent page
- Waivers of Consent page
- Consent of non-English speaking subjects page

Would you like to know when the website is updated?

Email Michelle at MMartin@chw.org and ask her to add you to the distribution list alerting staff of web updates.

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

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