Children's Hospital of Wisconsin

Human Research Newsletter

FEBRUARY 22, 2016 VOLUME 2, NUMBER 1

New CHW IRB Continuing Report Form

A new continuing report form has been posted in the IRBNet Document Library! The continuing report form is used to request renewal of the IRB approval period or to notify the IRB of study closure.

IRBs are required to conduct substantive and meaningful continuing review of research. At the time of continuing review, the IRB considers if there is any new information that would alter prior determinations, particularly with respect to the IRB's prior evaluation of the potential benefits or risks to subjects.

Accordingly, the IRB must determine that all of the following requirements for approval are satisfied:

- Risks to subjects are minimized.
- Risks to subjects are reasonable in relation to the anticipated benefits.
- Selection of subjects is equitable.
- Informed consent will be sought as required by §46.116 & ß50.25.
- Informed consent will be documented as required by §46.117 & ß50.27.
- When appropriate, the research plan makes adequate provisions for monitoring the data collected to ensure the safety of subjects.
- When appropriate, there are adequate protections to protect privacy of subjects and to maintain the confidentiality of data.
- When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of the these subjects.

The new continuing report form is designed to collect more specific information that will better support the IRB in determining if the study continues to satisfy the criteria for continuing IRB approval. The form also includes instructions to upload supporting documents (e.g., DSMB reports, multicenter trial reports) and current IRB-approved documents, such as the protocol, consent forms still in use, and the Investigator's Brochure. An updated policy on IRB Continuing Review is also in the works and the information requested in the new continuing report form will coincide with the new policy.

Effective March 7th, all continuing report submissions must include the new form. The old form will not be accepted after March 7th. Forms should always be accessed from the IRBNet Document Library to ensure the most current version is used.

INSIDE THIS ISSUE:

Notice of Proposed Rulemaking (NPRM)

On September 8, 2015 the U.S. Department of Health and Human Services issued a Notice of Proposed Rulemaking (NPRM) with the purpose of modernizing, strengthening and making more effective the federal policy for the protection of human subjects.

A total of 2,189 comments were received in response to the revised regulations proposed in the notice. To browse the comments:

- Go to http://www.regulations.gov/#!docketDetail;D=HHS-OPHS-2015-0008
- Scroll to the heading labeled "Comments" part-way down the page
- Click on "View All" next to the "Comments" heading
- Now you should have access to all of the comments, and can use the search box at the top to search among them.

A brief summary of comments submitted by the Secretary's Advisory Committee on Human Research Protections (SACHRP) is included below.

Complexity: While SACHRP strongly supports a number of the proposed changes (e.g., decreased burden on minimal risk research), we are deeply concerned that the complexity of the resulting Common Rule would seriously impair the ability of IRBs, research administrators, investigators, and clinical healthcare providers and institutions to effectively implement the new regulations. In addition, SACHRP has concerns as to whether the proposals as written will serve the stated objectives of enhancing subject comprehension and enhance participant protections.

1. SACHRP recommends that HHS conduct a comprehensive re-write of the NPRM through a concerted effort to simplify the proposed changes and to focus efforts on selected issues for which there is broad support by the public, investigators, IRB professionals, sponsors and other experts.
2. Prior to the publication of final rules, SACHRP supports a second publication of a NPRM that presents a simplified, focused set of proposals for further public consideration and comment.

Biospecimens and Data: SACHRP believes that the issues relevant to human subject protections in research involving information and biospecimens are virtually identical and overlapping in many or most circumstances. The risks that are associated with research with biospecimens largely flow from the information about the subject that is derived from specimen analysis. What sense is there in providing greater restrictions for research with a biospecimen than for research using an individual's full genome sequence derived from that specimen? Implementing different regulatory approaches to these two forms of research resources is not logical or defensible.

3. SACHRP recommends that the distinctions in the proposed regulations between research with subject information and research with biospecimens be reduced. The values of transparency, security, choice, and beneficence can be promoted on both domains through similar protections.

SACHRP comments also include specific recommendations relevant to biospecimens, the proposal to mandate single IRB review, the creation of excluded research and changes to exempt research, as well as revisions relating to consents.

Education Session for CHW Research Personnel

The next **Quarterly Education Session for CHW Research Personnel** will take place in March. We hope to see you there!

Topic: Minimum Recommended Clinical Research Coordinator Documentation in EPIC
Date: Tuesday, March 22nd
Time: 10:30am-11:30am
Location: CHW Auditorium

New IRB Policy – International Research

CHW has a new IRB policy titled *International Research*. The policy is posted in the Policies & Procedures section on the CHW intranet and in the IRBNet Document Library under Policy – International Research.

The policy states that the CHW IRB will apply the same ethical standards to the review and approval of international and US-based research. The policy describes requirements for local ethics committee approval from a foreign site as well as the need to obtain CHW IRB approval prior to CHW researchers conducting any study activities at a foreign site. Please contact the IRB Office with any questions about this new policy.

Pediatric Translational Research Unit

All pediatric affiliated research coordinators and assistants are cordially invited to a research networking session on:

Wednesday, March 9 from 1430-1530 in the Pediatric TRU (Center 2)
Call 266-6515 with questions
Treats provided!

Email bgissibl@chw.org if you didn't get the invite.

The Pediatric TRU will also begin a Research resources link on our page https://connect.chw.org/departments-services/clinical-departments/childrens-research-institute/pediatric-tru

If you have resources you would like to see here, please contact Beth Gissibl bgissibl@chw.org with suggestions and feedback. After the 3/22 education session, the video and slides will be saved onto the TRU webpage.

IRBNet Document Library

The IRB Office is reviewing and updating the submission forms posted in IRBNet. To ensure you are using the most recent version, please use the documents posted in IRBNet when preparing a new submission. Changes to documents will also be announced in this newsletter.

Documents recently updated:

- IRB – Continuing or Final Report Form

New documents available:

- Policy – International Research

Prior issues of this newsletter are posted under Research Newsletter.

The IRBNet Document Library houses submission forms, templates, policies and guidance documents. To access, log on to IRBNet. On the left navigation bar click "Forms and Templates". Then click the dropdown menu on top of the page and choose the second option "CHW IRB Milwaukee, WI Documents for Researchers".

Questions, Comments, or Suggestions

Your thoughts and recommendations for future newsletter topics are much appreciated! Please send your ideas and feedback to Julia Kennedy at jkennedy@chw.org.