Children's Hospital of Wisconsin

Human Research Newsletter

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Consent When the Parent of a Child is a Minor

An emancipated minor who is a parent of a child may consent to research participation of the child without the permission of the minor parent's own parent(s). Federal regulations, in the definition of "child," defer to state law, indicating that a child is someone who has not attained the legal age for consent to treatments or procedures involved in the research, under applicable state law where the research will be conducted. In Wisconsin, a child or minor is defined as someone under the age of 18. If a minor parent falls within this definition of a child and therefore is not permitted to consent to her own participation in treatments or procedures involved in the research, it would seem to follow that she could not consent for her child to be involved in such treatments or procedures in research.

In Wisconsin, there are a few exceptions to the adult age of 18, namely that a minor is emancipated as a result of being legally married. Therefore, a married minor is emancipated and can provide consent to her child's research participation. In addition, Wisconsin law allows a minor to consent (without parental consent) to screening for STD, HIV and pregnancy, and services for alcohol or drug abuse. Therefore, a minor could consent to her child's research participation if it involves only such treatments or procedures, as applicable. Wisconsin law also provides that a minor who has given birth is considered emancipated for purposes of obtaining an abortion without parental consent. Some organizations have interpreted this to mean a minor who has given birth is emancipated generally and therefore can provide consent for research participation of her child. It is not clear how Wisconsin courts would view this interpretation.

The CHW IRB may review research requests involving a minor's consent for research participation of her child, other than consent by legally married minors or research involving only treatments or procedures described above for which parental consent is not required, on a case-by-case basis with careful consideration of the nature of the research, anticipated benefits to the child, and potential risks to the child. Such research requests approved by the CHW IRB may be subject to further review at the institutional level before they can be initiated. Research with minors, pregnant minors and their fetuses and children requires special considerations to protect these vulnerable populations and involve complicated ethical issues as well as statutory and regulatory requirements.

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Pediatric Translational Research Unit

The Pediatric TRU is on the MOVE!

We will be moving to our new space on C2 (the old MACC Fund Clinic) on Thursday, May 14. Please note we will be open to seeing patients on May 13 and May 15 but unable to accommodate study needs on May 14.

Join us for our TRU Open House and LaTonda Tyler meet and greet!

Please join us on Tuesday, May 26 from 1300-1500 for our Open House and meet our new clinic assistant!

Come and learn about what TRU can do for you!

Educational Opportunities

Webinar: FDA Oversight and IRB Review of Studies that Include In-Vitro Diagnostics

5/14/15 12:00pm-1:30pm, Children's Corporate Center. When a study uses an in-vitro diagnostic (IVD) device that is investigational, the IRB must then determine whether it meets the criteria for an exempt device, a non-significant risk device, or a significant risk device. IRBs, investigators, and sponsors often struggle with this determination, and identifying the correct risk level.

The rapid growth and application of genomic testing in clinical trials and the use of IVDs to select patients for drug trials in particular pose unique challenges for IRBs and investigators.

PRIM&R's intermediate-level webinar on the use of IVDs will:

- Provide an overview of FDA regulatory framework in relation to IVDs
- Explain the application of FDA investigational device exemption regulations to studies with IVDs
- Highlight complex IRB scenarios and share processes developed by one institution through the use of case studies

Email jkennedy@chw.org if you are interested in attending this webinar.

Podcast: Rethinking the Vulnerability of Children in Comparative Effectiveness Research

Children present unique risks and considerations for researchers involved with Comparative Effectiveness Research (CER). In this conversation, F. Sessions Cole (MD, Assistant Vice Chancellor for Children's Health at Washington University School of Medicine in St. Louis) and Robert "Skip" Nelson (MD, Deputy Director and Senior Pediatric Ethicist in FDA's Office of Pediatric Therapeutics) discuss the nature of these vulnerabilities, the present state of the art in this emerging research, and specific ethical considerations encountered by experts in the field. The discussion concludes by specifically addressing things IRBs should be aware of when reviewing CER involving children. (30:38)
http://digitalcommons.wustl.edu/hrpopods/10/

Regulatory News

Draft Guidance on Individual Patient Expanded Access Applications Released by FDA

This guidance introduces and describes draft Form FDA 3926 (Individual Patient Expanded Access—Investigational New Drug Application (IND)). When finalized, draft Form FDA 3926 will be available for licensed physicians to use for expanded access requests for individual patient INDs. Expanded access requests are sometimes referred to as *compassionate use* requests. Individual patient expanded access allows for the use of an investigational drug outside of a clinical investigation for an individual patient who has a serious or immediately life threatening disease or condition and there is no comparable or satisfactory alternative therapy to diagnose, monitor, or treat the disease or condition. When finalized, draft Form FDA 3926 is intended to provide a streamlined alternative for submitting an investigational new drug application (IND) under § 312.23 for use in cases of individual patient expanded access. This draft guidance and draft Form FDA 3926 are not intended to apply to other types of expanded access requests, including requests for expanded access for medical devices.
http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM432717.pdf

IRBNet Document Library Updates

New documents available:

- IRB - Compassionate Use Request Form for Investigational Devices
- Guidance -Consent When the Parent of a Child is a Minor

Documents recently updated include:

- IRB – Categories of Exempt Review
- IRB – Categories of Expedited Review

Current versions of CHW IRB policies are posted.

Reminder: Research related photos/recordings should be described in the study consent form. The separate "consent to photograph" form is no longer required.

The IRBNet Document Library houses submission forms, templates, policies and guidance documents. To access, log on to IRBNet. On the left navigation bar click on "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.