Children's Hospital of Wisconsin

Human Research Newsletter

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Consent for Continued Participation When a Child Subject Reaches the Age of 18

A new IRB guidance document, *Consent for Continued Participation When a Child Subject Reaches Age 18,* is available in the IRBNet Document Library.

CHW policy *Institutional Review Board (IRB) Assent* requires that individuals enrolled as children with parental or guardian consent must be re-consented when they become adults unless the CHW IRB determines that a waiver of informed consent can be granted.

If a child turns 18 while study procedures or interactions are ongoing or identifiable data is still being accessed or used by the study team, the now-adult subject must provide consent to continue participation in the research.

If the study team anticipates that child subjects will turn 18 during the course of the study, Section N of the CHW Protocol Summary should describe plans to re-consent.

If study procedures are continuing, consent can be obtained at the next study visit with the current IRB-approved consent form.

If study procedures are completed, but identifiable data is still being accessed or used, the now-adult subject can be consented via phone and mail, as appropriate.

- Use the current IRB-approved consent form to obtain consent from the now-adult subject.
- Alternatively, Investigators may choose to obtain IRB approval to use an abbreviated consent form that describes relevant details about ongoing participation. An example is provided in the guidance document.

A waiver of informed consent will be considered in those cases where a subject's continuing participation constitutes no more than minimal risk and meets the other requirements for waiver under 45 CFR 46.116(d). Such a waiver may be considered at the time of initial or continuing review or amendment.

In situations such as biobanks or data registries, where continued use of samples and/or identifiable data meets the definition of "human subject research" the now-adult subject should provide consent. If it is not practicable to re-consent a subject, the Investigator could request a waiver of informed consent. If there is no ongoing contact with the subject and the samples/data are de-identified by deleting all links between any individually identifiable data and the samples/data, continued use would not require consent of a now-adult subject.

In situations where the study procedures are limited to data analysis, consent for continued participation is not required.

INSIDE THIS ISSUE:

New CHW IRB Amendment Form

A new amendment form has been posted in the IRBNet Document Library! The amendment form must be used to request approval for changes to an active study. Effective September 1, all amendment submissions must include the new form. The old form will not be accepted after September 1. Forms should always be accessed from the IRBNet Document Library to ensure the most current version is used.

Q&A

The IRB Office, TRU, and Research Compliance Office would like to share answers to some frequently asked questions. If you have recommendations for other topics to address in the future, please let us know!

Q: I plan to submit a pediatric clinical trial comparing an investigational drug to a placebo-control. There is no prospect of direct benefit for the placebo arm. In Section G of the CHW Protocol Summary Form, should I choose one Pediatric Risk Level for the study drug arm and a different Risk Level for the placebo arm?
A: Yes. FDA has indicated that administration of a placebo does not offer a prospect of direct benefit. The FDA does not consider the concept of enhanced safety monitoring or follow-up provided to subjects in a placebo arm to constitute a prospect of direct benefit. FDA expects the IRB to conduct a component analysis of each arm of a placebo-controlled trial. The placebo arm of a pediatric clinical trial should be considered under Level 1 (not involving greater than minimal risk) or Level 3 (minor increase over minimal risk with no prospect of direct benefit, but likely to yield generalizable knowledge about the subject's disorder or condition).

Q: If I plan to carry out a quality improvement project and publish the results, does the intent to publish make my quality improvement project require IRB approval?
A: The intent to publish is an insufficient criterion for determining whether a quality improvement activity requires IRB approval. IRB approval is required for activities that meet the HHS definition of "human subject research" or FDA definition of "clinical investigation".

Planning to publish an account of a quality improvement project does not necessarily mean that the project fits the definition of research; people seek to publish descriptions of nonresearch activities for a variety of reasons if they believe others may be interested in learning about those activities.

If you are unsure if your project requires IRB approval, please submit a Non-Human Subject Research determination in IRBNet.

Q: If I plan to use the Pediatric TRU for a study, should TRU staff be listed as research team members on the IRBNet registration page?
A: No, this is not required.

Q: I plan to use Epic or iNSIGHT to access PHI in order to prepare a research study (develop the research question, determine if there are a sufficient number of patients with a specific diagnosis). Is there a form I need to fill out?
A: Yes, A Preparatory to Research Form must be submitted to the Medical Records Department prior to using Epic or iNSIGHT for this purpose. The form can be found on the CHW intranet; click on Clinical Resources in the column on the left, then click on Research. These preparatory steps do not require IRB (Privacy Board) review.

Electronic Access to PHI for Research Monitors through EpicCare Link

Research Coordinators may submit a request to allow a research monitor to access the medical record within Epic, either onsite or remotely via a secure website. The policy *Electronic Access to PHI for Research Monitors through EpicCare Link* and form required to make this request will be posted online soon and are also included in the email with the newsletter. If you have any questions about this, please contact Julie Dais, HIM Service Manager in the Medical Records Department.

IRBNet Document Library

New documents available:

- IRB - Amendment Form
- Guidance – Consent for Continued Participation When a Child Subject Reaches Age 18

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.