September 2014

Human Subjects Protection Update (Special Communication)

IRB (Institutional Review Board) Boston Children's Hospital

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New Witness Signature Line for Use with Short Form Consents

A new witness signature line has been added to the English consent form template, to specifically address the role of the interpreter when short form consent is used to enroll a non-English speaking subject. The interpreter may serve as a witness to indicate that the information in the consent form was presented orally in a language the subject understands and the subject had the opportunity to ask questions before agreeing to participate.

The use of this witness signature only applies to protocols for which the IRB has determined that the short form may be used instead of a full length translation of the consent form. You will know if your IRB approval allows the use of a short form, because the approval letter will state "Use of the short form is permitted for this protocol per the conditions and procedures outlined in the Committee's policy." Please review your protocol's approval letter or call the IRB Office (ext. 57052) or your IRB Administrator if you are unsure if use of the short form is permitted for a particular protocol.

Effective immediately, in order for Interpreter services to assist in obtaining consent with use of the short form, the new witness signature line must be on the long form that the interpreter also needs to sign. Please note the following to make sure you have the appropriate witness signatures on the consent documents if you plan to utilize an interpreter:

1) All newly approved consents will contain the new witness signature section. If there are protocols in process of being reviewed, the IRB office will insert the appropriate language before releasing approval.
2) If you are in the process of creating a new protocol and consent form, please visit the BCH IRB website for the updated IC Template. It is posted on the IRB website and available within the protocol SmartForm.
3) At the next continuing review, or if you submit an amendment that includes revisions to the consent form, the revised witness signature will be inserted in your consent documents as appropriate.
4) Any investigator may request that their consent be revised by emailing the IRB administrator assigned to their department. You DO NOT need to submit an amendment in CHeRP.
5) In the event that a consent form has not yet been modified, and there is a need to enroll a non-English speaking subject and use of the short form is permitted as determined by the IRB, there is a separate Witness Signature Page available. This Witness Signature Page may be attached to the end of the full length consent form, as needed, until all consents have been modified. It is the PI's responsibility to obtain this attachment when using the short form. This can be found on the same page of the website as the short form translations.

Please find the updated English Informed Consent Template and separate Witness Signature Page on the IRB website:

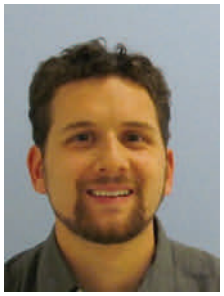
http://www.childrenshospital.org/research-and-innovation/office-of-clinical-investigation/information-for-researchers/informed-consent

IRB Satisfaction Survey: What did you think?

In an on-going effort to improve our services, we are asking the research community for feedback after they undergo the complete IRB review process. Final determination letters for all types of IRB review will now include the link IRB Satisfaction Survey asking to share your experience and offer feedback. This survey is brief and all responses are anonymous.

If you recently completed the IRB review process and would like to provide feedback, click the survey link: IRB Satisfaction Survey.

Welcome Daniel Alderson!



Daniel Alderson has recently joined us as an IRB Specialist focusing on protocols with multiple institutions in which more than one IRB has jurisdiction. This includes managing reliance agreements (also known as cede requests) among IRBs for shared protocols. Daniel joins us from the George Washington University in Washington DC where he served as Senior IRB Analyst. Prior to his regulatory work, Daniel spent several years in Chicago conducting research within pediatric psychology. As a new transplant to the region, Daniel enjoys exploring Boston and its New England surroundings.

Daniel can be reached at daniel.alderson@childrens.harvard.edu or (617) 919-1918.

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The Office of Clinical Investigation has been established to oversee the protection of human research subjects at Boston Children's Hospital. Children's is committed to safeguard the rights and welfare of all children, adolescents, adults and family members who volunteer to participate in research. To this end, the Office of Clinical Investigation upholds the principles of the Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects in Research, as the cornerstone of our mission, organization and daily activities.

- Have questions or comments about any of the articles in this newsletter?
- Need advice about your research?
- Want to know more about human subjects protection at BCH?

Please don't hesitate to contact the CCI and one of our staff will be happy to assist you.