Pediatric EducAtion Research Lunch Series (PEARLS)

IRB Submissions-What are your questions?

June 10, 2016

Objectives

- Answer and discuss regulatory submission issues. (pre-submitted questions will have priority)

Panelists (and their tips)

- **Katherine Garrett, MPH, CCRC, ELS,** Aflac Regulatory Team Lead
  - *Always put a header/footer on your consents with the date and page numbers to keep everyone on track with the most current version.*
  - *Make sure your consent is at the 8th grade reading level and keep sentences short (use bullets if you need to). Sponsor often push back, but IRB will not approve otherwise.*
  - *DSMP (Data Safety Monitoring Plan) on the application – be detailed*
  - *Renewals – include the number of male and female subjects, remember death is not a withdrawal*
- **Sarah Marie Huban, MA, CIP, CHRC,** Manager HPP & Research Regulatory Affairs, CHOA
  - *Tip to help IRB: when we send you an email with questions, please don't respond until you have all the answers*
  - *Tip to help you: if you have something that needs to be expedited or is unusual, call to discuss*
- **Margo Kamel, PhD, CHES, CCRC,** Clinical Research Coordinator IV, Emory DOP
  - *Get to know the people you are working with in the central offices*
  - *Be familiar with both CHOA and Emory IRB SOPs*
- **Shara Karlbach, WHNP-BC, CIP,** QA and Education Consultant, Emory IRB
  - *The cleaner the submission, the faster the process – use the Emory IRB website for tips and templates*
  - *Focus on consents and have someone else proof read*

Pre-Submitted Questions

What is the process for submitting to CHOA IRB and are there separate processes for other CHOA locations or satellite sites?

***Sarah Marie Huban**: All forms and the process are on the website (http://www.choa.org/Pediatric-Research/For-Professionals/Research-Administration/Institutional-Review-Board). The only site that requires a different process is Hughes Spalding – you must also submit to the Grady ROC (see below).*

What is the process for starting an Emory IRB approved study started at Grady?

***Shara Karlbach**: Studies at Grady must also be reviewed by the ROC (Research Oversight Committee): https://gradyhealth.org/static/office-of-research-administration/. Grady ROC meets monthly and Emory IRB keeps that in mind while reviewing.*

***Sarah Marie Huban**: If your study will be run at all the CHOA sites and has been Emory IRB approved, you can begin work at Scottish Rite and Egleston while you wait for Grady approval for Hughes.*

Pre-Submitted Questions

Is there a difference between preparing IRB submissions for grants vs industry sponsored studies?

***Shara Karlbach**: The process is the same. For grants, make sure you provide an actual protocol as opposed to the full grant application. We need to see details on how the protocol is carried out locally.*

***Margo Kamel**: Industry sponsors give you templates for everything, whereas grants you have to start from scratch. If your site is prime, the sub sites will look to your IRB submission as the example.*

Where can coordinators access instructions for CHOA IRB submissions?

***Sarah Marie Huban**: http://www.choa.org/Pediatric-Research/For-Professionals/Research-Administration/Institutional-Review-Board*

Pre-Submitted Questions

Where can coordinators access instructions for Emory IRB submissions?

***Shara Karlbach**: forms and instructions - http://www.irb.emory.edu/forms/new.html*

Instructional videos - http://www.irb.emory.edu/training/videos.html

Outreach and help clinics - http://www.irb.emory.edu/training/outreach.html

***Margo Kamel**: It's a good idea to book mark both IRB pages and read through their FAQs.*

***Katherine Garrett**: In the eIRB application, there is no "notes" section, but you can use the Miscellaneous Document section to upload comments or explanations.*

Pre-Submitted Questions

What's the relationship between the Emory and CHOA IRB's? If something is approved by the Emory IRB, but is covered under the IAA, what does the CHOA IRB want to know about the study?

***Sarah Marie Huban**: : The 2 IRBs are completely separate.*

(from CHOA IRB website):

- ***Studies that go to Emory:** Collaborative research that is conducted under the supervision of a PI who is employed by Emory, excluding CHOA research (see below)*
- ***Studies that go to Children's:** Collaborative Research in which the research is limited to the review of Children's medical records or collaborative research in which the research is conducted under the supervision of a PI who is solely employed by Children's, but involves the participation of other Emory-employed study personnel*

If a study is approved by Emory but will be conducted at CHOA, complete and submit the IAA (IRB Authorization Agreement Acknowledgment), found here: http://www.choa.org/Pediatric-Research/For-Professionals/Research-Administration/Institutional-Review-Board/IRB-Forms-Instructions

Pre-Submitted Questions

Can you explain what studies should be submitted to Western IRB (WIRB)?

Sarah Marie Huban: *For pediatric patients, you can use WIRB only when it is a CHOA PI.*

Shara Karlbach: *If it is an Emory PI and a pediatric study, you cannot use WIRB.*

Where are the Emory IRB's SOPs?

Shara Karlbach: *http://www.irb.emory.edu/policies/index.html*

Pre-Submitted Questions

Where are the CHOA IRB's SOPs?

***Sarah Marie Huban**: On Careforce: select "Policies & Procedures" from the menu on the right, then "Administrative and Operational" from the menu on the left, then click in the "Category" box under "Key Filters", select Research, then hit "Apply"*

Can we provide IRB SOPs to sponsors?

***Shara Karlbach**: yes*

***Sarah Marie Huban**: CHOA can provide you with a copy*

***Margo Kamel**: Very helpful to send to sponsors because it justifies your requests during the submission process.*

What is the process for documenting the assent process, such as appropriate discussion time?

***Sarah Marie Huban** : same as consent*

***Katherine Garrett**: cover page on the Emory document does a good job of explaining. It is important to document the process – the more robust the note, the better.*

Submitted Questions

Where can coordinators find guidance about the consenting and assenting process?

***Shara Karlbach**: Emory IRB has webinars on their website: http://www.irb.emory.edu/training/webinars.html*

***Sarah Marie Huban**: CHOA IRB can come do personalized training, practice consenting or observe your consent process.*

***Shara Karlbach**: Emory can also do personalized training and consent observations.*

***Terrell Faircloth:** FDA has a great FAQ document on consenting – email me and I can send you a copy (dana.faircloth@choa.org).*

***Katherine Garrett**: Emory CTAC (Clinical Trials Audit and Compliance) has great resources: http://www.ctac.emory.edu/clinical_trial_guidebook/informed_consent_process.html; http://www.ctac.emory.edu/clinical_trial_resources/Clinical%20Trial%20Tools.html*

***Shara Karlbach**: Emory IRB and CTAC are currently working together on a consent note.*

Pre-Submitted Questions

How do you have a consent translated into another language for a study?

***Sarah Marie Huban**: Depends, there are multiple options. You could use a certified translator, CHOA translation services or the sponsor may provide services.*

***Shara Karlbach**: check with others in your department to find out how it has been done previously.*

At which point is it appropriate to have a consent translated into another language? For example, if only one patient is consented and a translator is used, do we then need to have a translated ICF?

***Sarah Marie Huban**: CHOA IRB technically does not have a concrete number – call us to discuss.*

***Shara Karlbach**: After 2 subjects are seen that speak another language, call us to see if you need to use something besides the short form. It may depend on where you are with enrollment and what your expectations are to see additional patients speaking another language.*

Consent Scenario

Scenario: Study consents are usually in English, but when the majority of the patient population is Spanish, then it's appropriate to have a Spanish ICF. If the coordinator notices more than 2 people are consented for another language, such as Chinese, within a year, do you then translate the ICF to Chinese?

***Shara Karlbach**: call to discuss – depends on what you are expecting for the rest of the subjects. IRB will generally not "force" you to translate, but sometimes we can.*

Questions from the audience

Sensitive Study Status (examples: HIV, mental health, drug use) – how can we ensure these consents do not become part of the medical record?

***Shara Karlbach**: Unless your study is officially determined to be a "Sensitive Study", Emory OCR (Office for Clinical Research) will put the consent in the medical record. In general, Emory is trying to tighten up on what is deemed sensitive – it should only be used if the study/consent form would be the only mention of that diagnosis in the entire medical record. Even then, the consent is not protected from subpoena. For that level of protection, you would need a CoC (Certificate of Confidentiality): https://humansubjects.nih.gov/coc/index*

***Sarah Marie Huban**: In the past, all Marcus studies were given the "sensitive study" status, but that was not necessarily correct and they are trying to fix that moving forward.*

***Terrell Faircloth:** If a study should be sensitive but it was not requested or noted on the IRB submission form, will IRB pick it up?*

***Shara Karlbach**: yes*

***Margo Kamel**: Are CoCs only associated with federal studies or can you use it for industry sponsors?*

***Shara Karlbach**: It is federal, but can be used for other sponsors.*

Questions from the audience

How do you handle genetic screening tests that are required by the sponsor prior to enrolling in the study?

***Shara Karlbach**: you must consent first – if it is a required test to be eligible for the study, then it is research. There are "screening" and "pre-screening" consents. Emory IRB approval letters will start stating if/when the screening part of the study needs consent or if it is waived. For Genetics in particular, there is specific language that needs to be included in the consent for GINA (Genetics Information Nondiscrimination Act). MK: The language is available in the modular consent template to cut and paste: http://www.irb.emory.edu/forms/consent_toolkit/index.html*

***Sarah Marie Huban**: CHOA IRB is working on adding this to the new template will be available in the fall.*

With the new CITI modules that Emory is adding to the required training, will you be able to link your CITI profile between CHOA and Emory?

***Shara Karlbach**: yes, affiliates should be able to cross over within CITI. The new Emory required training can be found on the OCR website: http://www.ocr.emory.edu/training/index.html*

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