Human Research Newsletter

APRIL 30, 2019 VOLUME 5, NUMBER 2

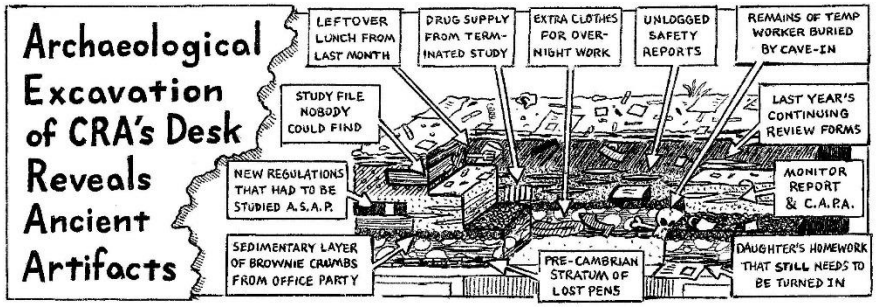
INSIDE THIS ISSUE:

Welcome New IRB Staff!

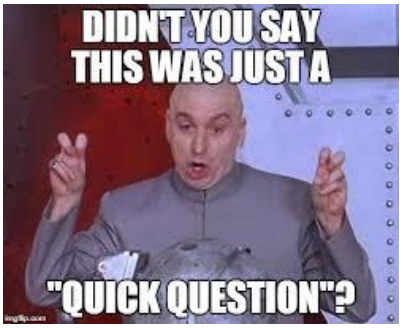
We are thrilled to announce the addition of two new staff members to the IRB office.

Laura Bezler is a new IRB Analyst who will be on site May 13, 2019. Laura holds an MS in Regulatory Compliance in Clinical Research and a BA in Biology. She comes to us from Northwestern University where she has been working as a Research Project Coordinator in the Feinberg School of Medicine – Comprehensive Transplant Center. She brings with her experience in managing complex, multicenter trials as well as working with the FDA.

"My name is Brandon and I've been with Children's Hospital of Wisconsin for about two weeks. I have nearly 5 years of high-level support experience, working for organizations like Advocate Aurora Health and Miracle Home Health of Wisconsin. I'm also a full-time student, graduating in December with a degree in Business Management Marketing. My fiancé and I have a dog named Sheba, and reside on the Milwaukee River in West Bend. I look forward to learning and working with everyone as my time with Children's continues to grow." Brandon Woodruff, our new IRB Executive Assistant, will be staffing the main phone line and email as well as assisting with administrative tasks, working on special projects, helping with reliance agreements and assisting with anything else we can think of to give him.



"I Have a Quick Question……."



……*or d-o-o-o y-o-u*? We receive **a lot** of calls and emails from study teams who have a "quick question." Many of these turn out to be much bigger questions than anticipated, and require more information for us to be able to provide an answer. Many of you have heard us answer with "it depends." This is because it does. So many answers to investigator and study team questions (even seemingly general ones) and any guidance we can provide, is very dependent on specifics of a situation or the context of a specific protocol or proposed research idea. One answer does not necessarily apply to all situations and studies. Also, answers may change when additional facts or information are introduced. When these "quick questions" turn into long, complicated discussions that were not planned on and for which we have no background information we may not be able to provide appropriate guidance without some research and/or lengthy discussion. We want to be able to provide ample, undivided attention to your questions and be able to prepare the best possible guidance.

In the interest of efficiency and providing the best guidance we can, we have two additional options for seeking out assistance from the IRB staff. If your question truly is a quick one and straight forward, please feel free to continue to call the main line at 414-337-7133 or send an email at CHWIRB@chw.org and we will assist. However, if in thinking through your question it seems it will require some discussion, and/or may be dependent on what your research or proposed research entails, then we encourage you to use one of these new options. Also, we may request that you utilize one of the other options when we get a question and realize that it may not be so quick.

1. We have developed a form to request a consult with the IRB staff. This can be found in IRBNet. The intent of this form is for you to gather and reference any relevant information to assist us in preparing appropriate guidance and preparing for discussion, as well as ensure that we plan for and schedule sufficient time to help. It will also help us route to the most appropriate person in the office who can help, and include others who may need to have input (such as Legal, Elizabeth (Institutional Official), Diane in Corporate Compliance or Jeff in the TRU).

2. IRB Open Office Hours are now available on **Tuesdays 10am - 12pm starting Tuesday May 7, 2019**. This is a time during which you can call or drop into the IRB office, and Michelle and Lori will be standing by to discuss any questions or issues, and provide guidance to study teams. We do ask that you come prepared with any materials or draft proposals related to your question or issue.

Did you know... in order to maintain hospital accreditation and compliance with the Joint Commission standards it is crucial that any skill performed on a Children's patient is only performed by Children's Hospital employees or providers who have competencies on file.

Who is considered a Children's Patient? A Children's patient is any person who is being seen for care at Children's hospital regardless if it is for clinical or research care.

What does this mean for my research? The Pediatric Translational Research Unit (TRU) is available to provide these patient care services or can direct you to appropriate personnel.

Follow-up: New Informed Consent Template

Now that the new ICF template has been available for a few months, we wanted to update study teams on a few things.

Which template do I use? The old one or the new one?

The new ICF template, revised in January, should be used for any **NEW** study submitted after January 21, 2019.

Any consent updates for ongoing studies (approved prior to January 21, 2019) should made using the pre-2018 consent template language. Any changes requiring a new consent document should also use the pre-2018 ICF template. Why you ask? Because we are not transitioning every study to the 2018 Common Rule requirements at this time, we want to avoid any appearance that a study reviewed under the pre-2018 Common Rule is being transitioned. Additionally, if updates are being made to a previously approved consent, and the new ICF form is used, this will require a complete re-review rather than a focused review of the proposed changes, which will significantly delay approval.

What if I need to change the template "black language"?

There may be instances when the template language needs to be altered because of the particular context of a study, or because of regulatory considerations, etc. While we want to maintain as much flexibility as possible, we also have a strong interest in maintaining consistency across our consent documents.

We have developed a process by which investigators can request a change to the template language. There is a new request form "Request to Change Consent Form Template Language" available in IRBNet with instructions. This form, along with a draft of the suggested language, must be submitted and approved by the IRB office **BEFORE** including these changes with your submission. If approved we will return the form indicating such and this form should be included with your submission as documentation that the altered language in the consent has been reviewed and approved. Please keep in mind that a request to change template language should not be used for preference in word choice or style. There needs to be a compelling, or regulatory reason, to justify the change. If a sponsor is requesting this change, the investigator should work with the sponsor to provide sufficient justification for consideration.

A request does not guarantee approval, and the IRB Chair or convened IRB may require specific modifications for the proposed change being requested. The IRB Chair or convened IRB will be the final arbiter if there is any disagreement.

Also keep in mind that this is a work in progress and there will be ongoing tweaks and updates to the ICF templates as we receive

feedback from all stakeholders and we continue to assess the best format and wording. Always start with the version of the template posted in IRBNet to ensure the most current one is used.

Not Quite Ready for Prime Time…….

In an effort to be mindful of all our investigators and to provide the highest quality, most efficient review of packages submitted, the IRB office expects each submission to be complete and "IRB ready." When this is not the case, the submission will require significantly more time during pre-review for unlocks and clean-up. This creates avoidable delays not only for the problematic submission but for those later in the queue and contributes to frustration with the IRB process.

We are implementing a new step in our review process to identify submissions sooner that may be problematic. If, during completeness review, it appears that a package will require a significant amount of clean-up or clarification, or has several documents or regulatory components missing, **we may withdraw the submission** and ask the study teams to address these issues and re-submit for review. This will necessitate the submission of a second package, and the submission will be placed at the end of the review queue. This process will allow the IRB analysts to focus on studies that are "IRB ready."

What you can do to ensure your study is "IRB ready" and improve the quality of your submission, particularly new studies:

- **Carefully check and recheck** ALL documents for typos, accuracy, and consistency across documents. For example, does the information provided in the registration page, the consent documents, the protocol summary, the Amendment or CR form, and the waiver forms (as applicable) all match or do they contradict each other?
- Check that ALL individuals listed on the study team have up to date CITI training **BEFORE** submitting. If you do not have a copy of their current training certificate – ask them for this to verify. (See our updated guidance in IRBNet for training requirements). Did you list the individuals using the name they used on their CITI registration?
- Be sure that **all** documents applicable to the study and required for IRB review are included. Consult the Submission Checklist available in IRBNet. If you are unsure about a document, contact the IRB office for guidance before submitting.
- Check and recheck forms to be sure ALL applicable fields are completed, all questions are answered.
- Be sure to have an understanding of what prior approvals are needed and ensure documentation or IRBNet signoff is present for all of these before submitting
- Be sure the project is described accurately and completely. The only thing the reviewers and IRB members will know about the project is what you tell them in the submission. If information is contradictory, confusing, not in lay terms, or missing they will

have questions and not be able to make a determination. **For example:**

- Is it clear exactly what is being done ONLY for research, clearly delineating that from anything being done otherwise for clinical purposes?
- Is it clear exactly what will be done with the data? Who has access? What data are being collected?
- Is the consent *process* clearly and completely described? Will assent be sought? How/where will this be documented? What is the plan for re-consenting if a subject reaches the age of majority during participation?
- Are all research risks described, and how these risks minimized and monitored clearly explained?
- Are the research procedures and time points clearly outlined?

We suggest a "buddy system" to help quality-check ("QC") your submission. Have a member of the research team who did not prepare the submission, or someone who is not as actively involved, read through to help catch errors and inconsistencies and determine if the documentation clearly conveys what the research entails. Your "buddy" can be 'IRB member-for-the-day' and review the submission using our tools and checklists. You can then return the favor by taking turns helping each other out.

Reviewer checklists are found on the HRPP webpages at https://connect.chw.org/en/departments-services/clinical-departments/childrens-research-institute/human-research-protection/Forms. These will show you what the reviewers are looking for, what information they need to make a determination and can be helpful in ensuring your submission provides the information needed.

What is the "Common Rule?"

This is essentially the Federal Policy for the Protection of Human Subjects promulgated by the US Department of Health and Human Services. This policy encapsulates the ethical principles outlined in documents such as the Belmont Report and the Declaration of Helsinki. This has been codified into separate regulations found at 45 CFR 46, subparts A, B, C, and D that govern the conduct of research involving human subjects in the US.

There are 19 Federal Agencies that have adopted Subpart A of the regulations, which is why 45 CFR 46 is often referred to as the "Common Rule."

Both FDA and OHRP oversee the treatment of human subjects in research, but have a separate sets of regulations. The FDA's jurisdiction is over treatments that could be approved as commercial products, and over any FDA regulated product that is used in research, while OHRP is

Comparison of HHS and FDA regulations can be found here

concerned with research either funded or conducted by the Federal government. Because of the nature of the research that FDA oversees, FDA codified separate (but similar) regulations rather than signing on to the Common Rule.

When does the Common Rule apply?
Except for human subject research that meets one of the exemption categories under 46.104, the Common Rule subpart A applies to all research involving human subjects conducted, supported, or otherwise subject to regulation by any Federal department or agency that takes appropriate administrative action to make the policy applicable to such research. Review your grant, contract or other agreement as well as the protocol to see if compliance with the "Common Rule" or "45 CFR 46" is required. OHRP is the oversight body for these regulations.

When do FDA regulations apply?
FDA regulations (21CFR parts 50 and 56) apply to all clinical investigations regulated by the Food and Drug Administration under sections 505(i) and 520(g) of the act, as well as clinical investigations that support applications for research or marketing permits for products regulated by the Food and Drug Administration, including foods, including dietary supplements, that bear a nutrient content claim or a health claim, infant formulas, food and color additives, drugs for human use, medical devices for human use, biological products for human use, and electronic products.

If you are conducting research that is both FDA regulated and federally-funded, both sets of regulations apply and the IRB applies the stricter of the two.

It is important for researchers and the institution to clearly understand what regulations they are obligating themselves to follow by entering into an agreement to conduct a research study. This is not a "regulatory determination that the IRB of record must make," is not based on "interpretation" or "judgment", but is rather an assessment of specific language contained in the protocol and/or grant, contract, or other agreement. If you are unsure what regulations you have agreed to follow, you can reach out to Lori Roesch, Research Integrity Manager.

Tis the Season…….For Staff Change Amendment Requests!

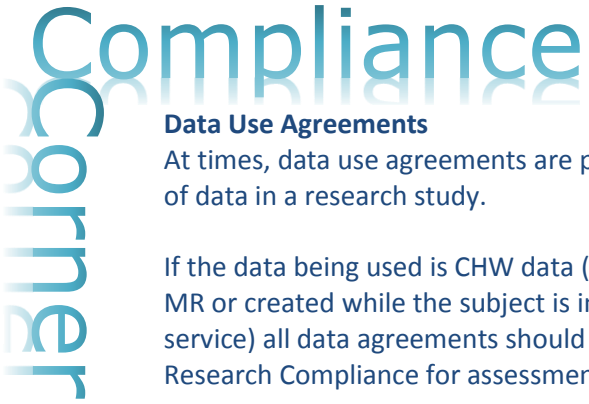
At any given time, we have many (non-PI) Staff Change Amendment requests in the queue for processing. During this time of year, the numbers rise quickly and we can have as many as 40-50 waiting for review. We know that everyone wants these to be processed quickly.

What can you do to help us review your request as quickly and efficiently as possible?

1. Ensure that the package only involves the addition or removal of individuals. Other changes (e.g., increasing enrollment

numbers, consent document revisions) require a different level of review and take additional time.
2. Ensure that all individuals being added are current on all required training. You should verify this before submitting your package.
3. Ensure that all documents affected by the change are updated (with tracked changes) and included in the package (e.g., Registration Page, HIPAA/consent waivers, sometimes consent/protocol summary – although we do not recommend ever including individual names on these documents).
4. Ensure that the package has been signed by the PI.

Failure to take these steps will result package unlocks and unnecessary delays processing your request.



Data Use Agreements
At times, data use agreements are put in place for the use of data in a research study.

If the data being used is CHW data (taken from the CHW MR or created while the subject is in a CHW clinic/ancillary service) all data agreements should be forwarded to CHW Research Compliance for assessment.

In these cases, the use of CHW data requires review and signature of the CHW Privacy Officer (Tom Twinem, VP of Corporate Compliance). All data use agreements also need to be kept on file at CHW.

Please be aware, sometimes the data use agreements are embedded in other documents sent from a sponsor.

Please review the documents to ensure CHW Corporate Compliance receives the documents required by HIPAA Regulations.

PEDIATRIC TRU UPDATES

EPIC Reminder: Jeff Crawford is your Research Epic Credential Trainer. If you ever have any research related questions, comments, or concerns please contact Jeff – jcrawford@chw.org or 414-266-7254

Education Opportunities

Small Group Education Sessions-TRU and IRB Staff

Join IRB and TRU staff for informal presentations and small group discussions of select research topics. Space is limited, however, the same topic will be discussed at the two sessions each month. This will

also be an open discussion and a chance to bring your questions or get assistance with EPIC or IRBNet.

These will meet in the TRU: Center 4 South, Main Hospital

May 14th, 2019 @ 2:00pm, Mock Study Submission, Part 1 of 2

May 23rd, 2019 @ 10:00am, Mock Study Submission, Part 2 of 2

June 18th, 2019 @ 10:00am, "Consent Template Change Request; How and When to Utilize" and TOPIC TBD

July, 9th, 2019 @ 2:00pm, "Consent Template Change Request; How and When to Utilize" and TOPIC TBD

July 25th, 2019 @ 10:00am, "Children's Experience Promise" and TOPIC TBD

August 6th, 2019 @ 2:00pm, TOPIC TBD

August 22nd, 2019 @ 10:00am, "Children's Experience Promise" and TOPIC TBD

Quarterly CRI Education

June 4th, 2019 @ 9:30am, "Identifying Common Submission Problems to Improve Quality"

IRBNet Document Library and Website Updates

The IRB office is reviewing and updating forms and documents posted in IRBNet and on the HRPP webpages. To ensure you are using the most recent version, please use the documents posted in IRBNet when preparing a new submission.

Forms/guidance/Web pages recently posted:

- New Form: CHW IRB Consultation Request
- Updated Form: Continuing Review Form
- Registration page updated in IRBNet
- FAQs on the HRPP webpages has been updated

For more information and updates on education opportunities visit the HRPP webpages

Children's Hospital of Wisconsin Human Research Protection Program/Institutional Review Board

Children's Corporate Center
999 North 92nd Street, Suite #120
Milwaukee, Wisconsin 53226

We're on the Web!

https://connect.chw.org/hrpp

Questions, Comments or Suggestions:

Your thoughts and recommendations for future newsletter items are much appreciated. Please send ideas and feedback to Michelle Martin, CIP, CCRP at MMartin@chw.org