Children's Hospital of Wisconsin

Human Research Newsletter

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Staffing Update

In the upcoming months there will be 2 IRB Specialists out on maternity leave. Cassie will out starting sometime in September and returning in December. Angela will be out starting sometime in late November and returning in February.

While they are on maternity leave, there will be coverage for their workload. However, if you try to contact either of them during that timeframe, and you have not received a response in a reasonable time, they may be out on leave so please let us know and send your email to the main email at CHWIRB@chw.org.

Certificates of Confidentiality

Certificates of Confidentiality are issued by the National Institutes of Health (NIH) and other HHS agencies to protect identifiable research information from forced or compelled disclosure. They allow the investigator and others who have access to research records to refuse to disclose identifying information on research participants in any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level. Certificates may be granted for studies collecting information that, if disclosed, could have adverse consequences for subjects or damage their financial standing, employability, insurability, or reputation.

These are typically requested by a sponsor, but can be requested by a PI of an investigator initiated study. Study teams should be aware when these are issued for a study. There is language informing subjects that must be included in the consent form. Sample language is provided by the NIH to include in the consent. There are also some limitations to this certificate.

For more information see the Information Sheet on the HRPP web pages or:
https://humansubjects.nih.gov/coc/faqs

Auto-reminders To Submit Continuing Review for Studies Turned On

As many have already realized, the IRBNet feature to send automatic reminders to submit annual continuing progress reports has been turned on. These are courtesy reminders to help avoid studies lapsing. IRBNet will automatically send an email reminder to those with full project access at 90 days, 60 days, and 30 days prior to expiration date. The 30 day reminder will be marked as "URGENT."

The reminders will generate even after a CR package has been submitted and approved. Unfortunately, the system is not able at this time to turn these off once the CR is submitted. The reminder notification email does indicate to disregard the reminder if the CR has already been submitted. We understand some study teams may find this to be an annoyance; however, they are important reminders for those studies in danger of lapsing. Manually determining which projects are getting close to expiration, and which have **not** had a CR submission, and then manually sending reminders is exceedingly time consuming and not an efficient use of IRB office resources. Therefore, these will continue to be generated automatically. If you are timely in getting these CRs submitted we thank you and appreciate your tolerance of these reminders.

Ideally, CRs should be submitted **no later than 60 days prior to project expiration.** This is to ensure that there is time before expiration to resolve any questions or issues that the IRB review committee may have prior to issuing the approval. It is challenging when the IRB office receives a CR submission days before expiration. Other reviews and tasks have to be set aside to address these to avoid a lapse. If submitted too close to the expiration date, sometimes it is not possible to avoid a lapse depending on whether there are issues in need of resolution to keep the project

in compliance with the regulatory criteria for approval. Thus, having reminders go out starting at 90 days may help mitigate this problem in the future. Please remember that even if it does not appear that the IRB is working on your submission, there are many tasks that cannot be visualized on the researcher side of IRBNet. If a deadline is approaching and you desire to know the status of a submission, please email CHWIRB@chw.org.

Planning for PI Absence: Temporary Change in PI

Who is an investigator?

21 CFR 312.3
HHS FAQs

Investigator responsibilities

FDA Guidance
HHS FAQs

The **Principal Investigator** is ultimately responsible for all conduct of a research study. Even when responsibilities are delegated to other investigators, the PI is considered the leader of the team and bears the ultimate responsibility.

Study teams should have a back-up plan for when a Principal Investigator will be gone for extended period of time. Another investigator (when there is one) could take over for short periods of time (a week of vacation for example) provided that individual has the requisite qualifications to perform those research duties. However, the IRB office strongly encourages, in light of best practice, that when a PI is going to be unavailable for an extended period, he/she should formally delegate a change in PI responsibility with the IRB.

This would be handled as an amendment requesting the PI change, and then a follow-up amendment to revert the responsibility back when the "regular" PI is again available. Assuming the "acting" PI has the same qualifications as the "regular" PI the approval could be obtained quickly.

Additionally, if there is a sudden and unexpected situation in which a PI is no longer able to manage a study (sudden departure, death or medical emergency, etc.) the IRB office should be promptly notified of this. This would be considered and unanticipated problem, and study teams should submit this information via a reportable event/unanticipated problem package submission and provide the plan to address the situation.

Related to this – it is CRITICALLY important that when a PI leaves the institution, his or her active studies are transferred to another investigator or are formally closed with the IRB. This should occur BEFORE the investigator leaves the institution so the PI, as the responsible party, can sign off on the closure or the transfer.

As a reminder, the new PI should be submitting a memo to the IRB indicating their acceptance of the responsibility as PI and committing to their responsibilities as PI. This should be

What does the IRB want from me?

submitted with new studies, as well as with amendments to change the PI. A new memo template for this purpose is available in IRBNet and on the HRPP webpages.

Update to the CHW Registration Page in IRBNet

The CHW Registration Page has been updated regarding enrollment of non-English speaking subjects to avoid confusion with the use of the word "exclude" (which is related to protocol exclusion criteria) v. anticipating enrolling non-English speaking subjects based on the subjects likely to be encountered by the local investigators.

We have updated this question to more accurately reflect the intent. This question intends to determine whether or not the PI thinks there may be non-English speaking potential subjects encountered that the PI would like to enroll – NOT whether non-English speaking subjects will be excluded based on the inclusion criteria listed in the protocol. The question has been modified to read:

"*Do you anticipate enrolling non-English speaking subjects? (explain in the protocol summary.)*
REMINDER: Consent, Assent and HIPAA forms should be translated into the subject's language if you anticipate enrolling subjects who speak only that language."

If you answer **"yes"** it means you think your team will likely encounter a non-English speaking subject, based on the population you routinely serve or plan to target. Per CHW policy, you then need to submit translated documents (not the short form) for the appropriate, anticipated language(s). It is suggested that an amendment be submitted with the translated documents once the IRB has approved the English versions of the documents to avoid additional translation costs.

If you answer **"no"** it means you do not anticipate you will encounter potential subjects who do not read/speak English. In this case, approval of the short form consent should NOT be requested with the new project submission (doing so indicates non-English subjects are in fact anticipated in which case fully translated documents should be submitted.) If an unexpected potential non-English speaking subject is later encountered, and there is no time to have the consent documents translated, an amendment should be submitted to obtain approval to use the short form consent process for that particular patient. This is intended to be used one time for the unexpected subject, after which additional subjects speaking that same language would no longer be unexpected. If additional subjects who speak that same

language are to be enrolled, full documents must be translated and submitted for approval by the IRB.

For active studies, at the time of the next amendment or continuing review, please update the registration page to answer this question in its new form and indicate you are doing so on the amendment submission form.

Deferrals and Reliance Agreements

Good news! The CHW IRB office staff members are working hard to make the reliance/deferral/collaborative research initiation process more organized and efficient. One of the ways we are improving this process is through a specific email address: CHWIRBReliance@chw.org. If you have any questions relating to these topics or would like to begin the process, please contact us through this email. Cassie Baumgart has taken the lead role in assisting with deferrals.
If you have a deferral involving MCW/BCW/FH, you may also fill out the "Investigator Reliance Request form" found on MCW's Human Research Protection Program website: http://www.mcw.edu/HRPP/Forms.htm and attach it to your email. (This form will also be placed on the CHW Human Research Protection Program website in the near future.)

More guidance will be released on this topic in the future.

What Do I Do With That Barcode?

We have received questions of late regarding the status of the barcode, which is in the CHW consent template, and whether or not this is to be included on the consent forms.

Per corporate compliance, this barcode must remain on the consent forms submitted, and IRB office staff will be looking for this on pre-review of submissions. When a consent is being included in the medical record and scanned into EPIC, this bar code indicates to Health Information Management (HIM) that the consent is research-related and requires special consideration in the event of a request for release of records.

This is NOT the case for the HIPAA documents, as these do need to be included with a legal release of records, so the barcode should not be included on the separate HIPAA authorization forms. HIM is responsible for determining whether the HIPAA portion of the combined HIPAA/Consent gets released, so the barcode should appear when the consent/HIPAA are combined.
In summary:
HIPAA alone – no barcode
HIPAA + Consent – barcode
Consent alone - barcode

Grant Congruency Checks

As a reminder, there is a regulatory requirement for there to be a grant congruency check for federally-funded research projects. This is to ensure that the research described in a grant application matches what is described in the corresponding protocols which the grant will fund.

The IRB office is increasing our diligence in documenting grant congruency for federally funded studies when a CHW investigator is the grant awardee (this is not required in the case of sub-awards). As such, you may see additional questions regarding this if applicable to your study.

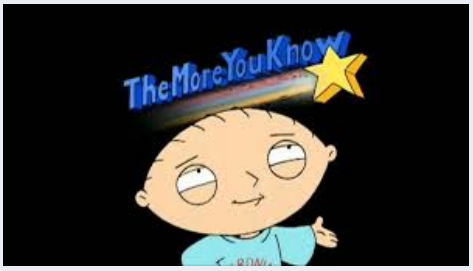
Investigators should keep in mind the potential for the need to update a grant application via the amendment process should there be major changes to their funded project so the grant congruency review can be conducted if necessary.

Managing Documents in IRBNet Revisited: Deadline for Following the Proper Process

About a year ago we began training teams on the proper way to manage documents in IRBNet (the way the IRBNet developers intend for documents to be tracked) – using the pencil icon to update an existing document when there is a revision versus attaching revised documents as "new." There were instructions provided in the newsletter - Volume 2 Issue 2 from May of 2016. This is also explained in the IRBNet training resources which were provided in the same issue. When IRB staff provides IRBNet in-person training this is also demonstrated and explained. Managing documents in the manner intended by the system, by having a document revision history in one place, allows IRB reviewers (and study staff) to find the most current version, and the previous versions for comparison, much more efficiently.

Now that it is been a year since providing these instructions and working with teams to demonstrate this way of managing documents, **the IRB staff will begin enforcing this starting January 1st 2018.**

What this means is that after that date, if a package is submitted with **revised** documents uploaded as **new**, rather than as a revision to an existing document, submitters will be asked to correct this in the package as part of the pre-review process. We do not want to delay your approvals so we are giving you plenty of time to get used to this process before final implementation.



For more information and updates on education opportunities visit the HRPP webpage at: https://connect.chw.org/departments-services/clinical-departments/childrens-research-institute/human-research-protection/education-training

If anyone still has questions about how to do this, or would like additional training/demonstration please contact Michelle at MMartin@chw.org so this can be provided in the next few months prior to this deadline.

Educational 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 be held in the TRU. Upcoming topics are to be determined, so check back at the website for more information and watch for an email from Jeff Crawford from the TRU with more details.

If you have topics of interest you would like to see discussed at an upcoming meeting, please email Jeff at JCrawford@CHW.org or Michelle at MMartin@CHW.org.

- **Tuesday August 8,** 2017 at 2 p.m. – Research Budgets + Open Forum
- **Thursday August 24**, 2017 at 10 a.m. - Research Budgets + Open Forum
- **Tuesday September 4**, 2017 at 2 p.m. – TBD
- T**hursday September 21,** 2017 at 10 a.m. – TBD
- **Tuesday October 10**, 2017 at 2 p.m. – TBD
- **Thursday October 26**, 2017 at 10 a.m. – TBD
- **Tuesday November 7**, 2017 at 2 p.m. – TBD
- **Tuesday December 4**, 2017 at 2 p.m. – TBD
- **Thursday December 21**, 2017 at 10 a.m. - TBD

CRI Quarterly Education Session

The next quarterly education session will take place on Monday September 11, 2017 at 8:15 a.m – Children's Hospital Auditorium

The speaker will be Ryan Spellecy, PhD – Associate Professor of Bioethics and Medical Humanities, and Psychiatry and Behavioral Health. Dr. Spellecy is an extremely engaging speaker whom you won't want to miss.

Please forward your questions or topics to address to Jeff Crawford at JCrawford@chw.org in preparation for the session.

REMINDERS AND TIPS

- At the time of continuing review the IRB requires a summary, using the summary tool provided in IRBNet and on the HRPP webpages, of all new information about the study that has accumulated over the course of the previous year. At this time, the IRB looks at the study as a whole to assess whether or not the regulatory criteria for approval are still met. This includes reviewing the full picture of any changes to the protocol through previous amendments as well as reviewing the scope of events and new information that has transpired over the previous year. Examples include adverse events that have occurred, instances of non-compliance in the form of protocol deviations or non-compliance with regulations regarding the conduct of human research, new findings or interim conclusions about the study, etc. This summary log should include **BOTH** events/ information that have already reported promptly via a reportable event submission, and those things which did not require prompt reporting. To save time in preparing a continuing review submission and to avoid missing some of the information, it is strongly recommended that study teams record events and information on this log **throughout the year as they happen or the team becomes aware of them,** so this summary is already compiled when it is time to submit the continuing review.
- It is not acceptable to make changes to a project or modify documents as part of a continuing review submission. Modifications to documents in a CR submission should ONLY be made when specifically requested by the IRB. Any modifications to the project or its documents must be submitted as a **separate** amendment package.

Discovery Channel Documentary: *First in Human: Before the Breakthrough Comes the Trial*

This three part series airing in August gives an up-close look at how advances in medicine are made at the NIH Clinical Center, portraying the hopes and setbacks of patients, doctors and nurses seeking cures.

The NIH Clinical Center continues to work on cutting-edge treatments for the world's most deadly and damaging diseases, and is where thousands of researchers train for their careers in biomedical research and medical practice.

Airs Starting **August 10th, 2017** on the Discovery Channel

For more information: https://www.cc.nih.gov/ocmr/firstinhuman/

Among the many advances made at the NIH Clinical Center, some of the most notable include the discovery of biomarkers for cardiovascular disease, using fluoride gels to treat dental caries, prescribing lithium to treat depression, developing the first drugs to treat HIV and AIDS, using immune therapy for metastatic melanoma, creating innovative imaging approaches for prostate cancer, and testing the first in human Ebola vaccines in addition to new vaccines for malaria, influenza and Zika virus.

While the series focuses on a few brave patients and their doctors and nurses, more than 1,000 staff members across the intramural research program and 125 patients voluntarily participated in this production. For more than a year, NIH staff worked behind the scenes to enable this complicated production in ways that diligently protected the integrity of hospital operations as well as the safety and privacy of patients and staff.

IRBNet Document Library and Website Updates

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

Website content added or updated:

- Information sheet – Certificates of Confidentiality

New forms added to the IRBNet library and Website:

- PI acceptance of responsibility memo template **(New)**
- Reportable event log **(Updated)**

Would you like to know when the website is updated?

Email CHWIRB@chw.org and ask to be added to the distribution list alerting staff of web updates.

Questions, Comments or Suggestions:
Your thoughts and recommendations for future newsletter items are much appreciated. Please send ideas and feedback to CHWIRB@chw.org

Thank you for partnering with us to protect human subjects and for your commitment to conducting quality research.

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

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We're on the Web!

https://connect.chw.org/hrpp