Children's Hospital of Wisconsin

Human Research Newsletter

APRIL 27, 2017 VOLUME 3, NUMBER 2

INSIDE THIS ISSUE:

New Process for Requesting Human Subject Research (HSR) Determination

The IRB Office has developed a formalized process for requesting a determination from the IRB office regarding whether a project is human subjects research.

If a project meets the definition of non-human subjects research, IRB review, approval and oversight is not required. Investigators can self-determine, using the tools provided on the website. However, if a written determination is desired, or it is unclear to the PI whether a project is human subject research, investigators can request a written determination from the IRB.

The request form with instructions, as well as a guidance document with working definitions, can be found on the HRPP website on the Resources and Guidance for Researcher page under the heading "IRB Review of Research" at: https://connect.chw.org/departments-services/clinical-departments/childrens-research-institute/human-research-protection/research-resources.

Contacting the IRB Office

The IRB office has a new main phone number and office email address. If study teams have a general question that does not need an immediate answer, or a general comment, these can be left on the main number voice mail or sent to the general email. These are monitored by the specialists and any communication requiring a follow-up will be responded to as soon as possible but no later than the end of the next business day.

The intent is to improve efficiency in the office work flow with a way for teams to leave messages with general, not time sensitive questions and comments that don't need immediate responses. This should help free up the specialists to continue processing submissions. The greeting has instructions if the call is urgent.

If teams need to contact a particular person, either due to the nature of the communication, or because they have been working with someone on a specific issue, they should still contact that person directly.

IRB Office Main Phone Number: 414-337-7133
IRB Office General Email: CHWIRB@chw.org

HRPP Web Pages Reorganized

The HRPP website has been available for almost a year now. As content has grown, and will continue to be added, it was felt that some reorganization was needed to simplify the layout, while still managing continually growing content. The goal is to make information easier to find and access and to make updates and maintenance more efficient.

The page structure will be limited to several key pages that will then link to various content. The Resources and Guidance for Research Page has been organized topically, like an index or table of contents, with a list of links related to each topic. These links will include things such as: internal information sheets/guidance documents on a topic, HHS or FDA guidance, associated forms and templates, relevant policies, and links to external resources that may be helpful regarding a particular topic. This provides an organizational structure that lists research topics with any associated documents related to that topic grouped together.

For example, the previous web pages regarding consent have been deleted. Instead, the content that was on those pages is included on information sheets to which there is a link on the Resources Page under the topic of Assent/consent/parental permission. This topical heading also includes links to relevant forms and policies. This will continue to be updated in terms of content and organization to make finding information as simple as possible. Suggestions are always welcomed and can be submitted from the landing page at:
https://connect.chw.org/HRPP

As we continue to update, we are also planning to add pages that organize by document type, rather than by topic, which some may find more appropriate in some situations. These pages will compile links to documents of a certain type: such as all policies together on one page, all forms together on one page, and all guidance documents on one page.

The re-organization includes two new pages:

IRB Office Updates: When there is new information, process changes, changes or clarifications to policy or procedure, etc. this will be posted on this page as a more immediate means to communicate these updates. This can be checked by study teams regularly to get up –to- date information in between newsletters and education sessions. Also, we will continue to send blast emails in real time as deemed appropriate, but these may be missed or may not include everyone who needs to know since the distribution list is constantly changing. This is another way to provide updates in a timely manner.

Common Issues and Findings: This page will provide information on common issues seen in submissions that require correction. We plan to post common problems when we see a trend, along with the correction, until policies and guidance documents can be updated. This should also be checked frequently to help avoid common issues that cause delays in processing.

There are plans to create an FAQ page in the future, so please

New page structure HRPP web pages:

Human Research Protection Program (landing page)

- IRB Office Updates
- Common Issues and Findings
- Resources and Guidance for Researches
- Education
- Newsletter
- Policies (coming soon)
- Forms (coming soon)
- Guidance documents (coming soon)

send questions to help get us started.

Required Investigator Sign Off on Submissions to the IRB

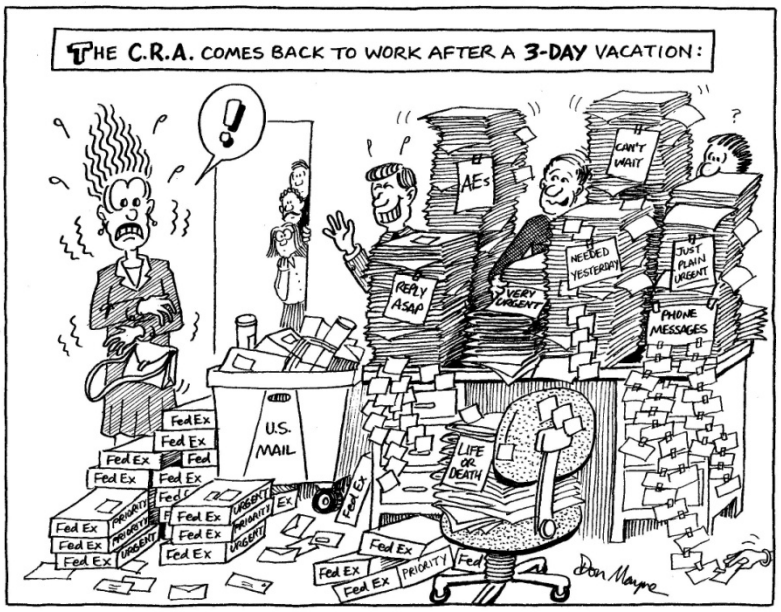
As detailed in a blast email from 03/09/2017, beginning May 1st, 2017 the IRB office will be enforcing the sign off by the PI on all packages submitted to the IRB Office. See the IRB Updates web page for details. The PI can sign off by either:

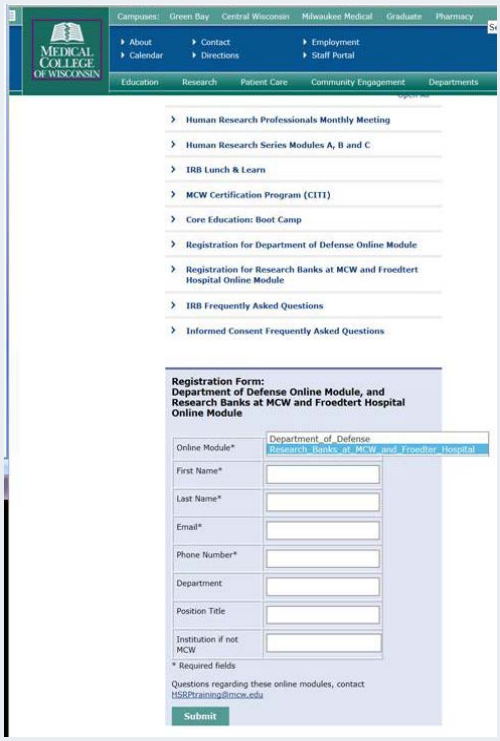
1. Signing the package electronically in IRBNet
2. Hand signing a memo that indicates the package has been reviewed and the PI is in agreement. This memo would then be uploaded to the package.
3. Responding to or sending an email to the coordinator indicating review of the package and agreement. A copy of this email can then be uploaded into the package.

To see entire email: https://connect.chw.org/departments-services/clinical-departments/childrens-research-institute/human-research-protection/IRB-office-updates

Additionally, we will also be requiring that any Investigators also sign off, via one of the methods above, when:

- Investigator is identified and included with the initial submission. Investigator would need to sign the new project package to indicate awareness of involvement with the study.
- An investigator is added to the study via an amendment. The investigator would need to sign the amendment package to indicate awareness of involvement with the study.





Banking Education Module on D2L

Questions and confusion on banking is common. There is a helpful module available through D2L.

D2L (Desire to Learn) is a Learning Management System used by MCW, similar to Children's University. To set up an account in D2L and register for the module :

1. http://www.mcw.edu/hrpp/TrainingandEducationalResources.htm
2. Scroll to bottom of the page
3. Fill out the registration form
4. You will receive an email with instructions. There are different instructions depending on whether you are an MCW employee or external (such as CHW) – although both can create an account to register for this module


An account has been created for you in Desire2Learn, the Medical College of Wisconsin's learning management system.

Please use your MCW email/network username (*not* your complete email address) and password or eBridge credentials to

External users only (i.e. you do not have an MCW email address or access to eBridge):

1. Set up a password
2. Log into Medical College of Wisconsin using your username cbaumgart@chw.org and password

5. External users (not MCW) will need to follow some additional steps to access the module after their D2L account is created:
    1. Login to https://mcw.desire2learn.com/d2l/login and enter your credentials
    2. Scroll down to the bottom to "My Courses" and follow the instructions to watch the video on banking.

OHRP - New Videos in Research Involving Prisoners (Subpart C)

OHRP has created two new short webinars about research involving prisoners and the special protections laid out in subpart C of the HHS regulations. Developed by OHRP staff, these videos are 15-20 minutes long and are designed to provide a deeper understanding of specific issues related to the HHS regulations and policies.

Click the links below to go directly to the videos:
Prisoner Research 1: 45 CFR 46 Subpart C—Basics (16:23)

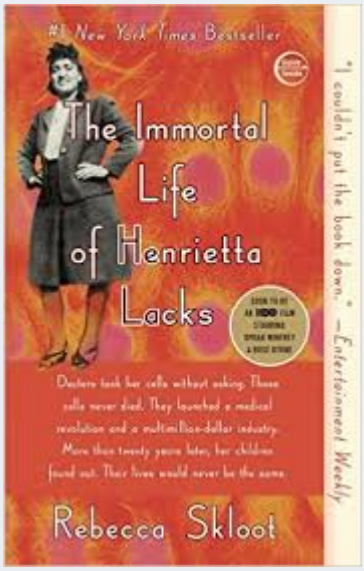
Prisoner Research 2: Considerations When a Subject Becomes a Prisoner (18:16)

You can view these, and many other resources, at:
https://www.hhs.gov/ohrp/education-and-outreach/online-education/index.html

REMINDERS AND TIPS

- When listing entities that will potentially received PHI on HIPAA forms, the CHW IRB should NOT be listed per corporate compliance.
- When submitting a continuing review, there should be NO modifications or changes to the project included. This includes changing or updating the registration page, unless the IRB has specifically requested this to correct information. We have noticed that sometimes the staff on the registration page is updated at the time of CR rather than by submitting an amendment. If there are **any** changes to the project, including staff, change in anticipated enrollment, etc. these changes need to be submitted via a separate amendment.
- Remember to update staff in a timely manner when the composition of your study team changes – to update the IRB on additions as well as removals. This should be done via an amendment, and as close as possible to the time of the change.
- When submitting an amendment, this is a good time to check that all study staff listed is current. If teams notice updates are needed, this can be included as part of the Amendment. This can help ensure study team lists are kept as current as possible (particularly when staff leaves or is not longer part of the project) in the event an amendment at the time of the staff change was not completed.
- When submitting a response/follow up package to address required changes or modifications, make **only** the changes specifically referred to in the "Modifications Required" letter. If there are multiple ways to address a modification, clearly explain that change in the cover letter submitted with that package. If additional modifications are needed a new amendment package is needed.

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



Henrietta Lacks was a 31-year old mother of five in Baltimore when she died of cervical cancer in 1951. Without her knowledge, doctors treating her at Johns Hopkins took tissue samples from her cervix for research. They spawned the first viable, incredibly productive, cell line – HeLa. This book is a #1 New York Times bestseller and fascinating from the perspective of human subjects protection.

https://www.amazon.com/Immortal-Life-Henrietta-Lacks/dp/1400052181

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. Upcoming sessions are to be determined, but check back at the website for more information forthcoming, as well as watch for an email from Jeff Crawford from the TRU with more details.

- **Tuesday May 9,** 2017 at 2 p.m. – TBD
- **Thursday May 25**, 2017 at 10 a.m. - TBD
- **Tuesday June 6**, 2017 at 2 p.m. – TBD
- T**hursday June 22,** 2017 at 10 a.m. – TBD

CRI Quarterly Education Session

Lessons Learned: Panel Discussion with Clinical Research Coordinators.

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

This will be held in the Children's Hospital Auditorium from 10:00am to 11:30am.

Pediatric TRU Updates

Welcome back Beth! Beth Gissibl has returned from her maternity leave. Beth is working part time for the next several weeks (generally Monday and Thursday), returning full time in June.

The Immortal Life of Henrietta Lacks – the movie!

Premiered this month on Home Box Office (HBO), "Oprah Winfrey and Rose Byrne star in this adaptation of Rebecca Skloot's critically acclaimed, best selling non-fiction book of the same name. Told through the eyes of Henrietta Lacks' daughter, Deborah Lacks, the film chronicles her search, along with journalist Rebecca Skloot (Byrne), to learn about the mother she never knew and understand how the unauthorized harvesting of Lacks' cancerous cells in 1951 led to unprecedented medical breakthroughs, changing countless lives and the face of medicine forever."

http://www.hbo.com/movies/the-immortal-life-of-henrietta-lacks

"How many IRB members does it take to screw in a light bulb?"

Author Anonymous

As documented in 45 CFR 46.107(a), this review board must consist of five or more members, and at least one of these members must possess a background in Electrical Engineering. In addition, at least one of the members must come from a home without any electricity. Any member of the IRB who owns stock in an electrical utility or who regularly pays bills to an electrical utility should recuse themselves from participation in the review of this research.

If the bulb should burn too brightly, burn too dimly, or flicker, then an adverse event report should be sent to the IRB (21 CFR 312.32). If the light bulb is dropped, then a serious adverse event report should be sent to the FDA by telephone or by facsimile transmission no later than seven calendar days after the sponsor's initial receipt to the information. If this is a multi-center light bulb trial, then a data and safety monitoring board (DSMB) may be needed (NIH Policy for Data and Safety Monitoring, June 10, 1998, http://grants.nih.gov/grants/guide/notice-files/not98-84.html, accessed on October 9, 2002). The DSMB should review any adverse event reports and interim results. If the clinical equipoise of the light bulb is lost, then the DSMB should terminate the study and provide all previously recruited light bulbs with the best available light bulb socket.

In order to maintain scientific integrity, the use of a placebo socket may be necessary. The placebo socket should have the same taste, appearance, and smell of a regular socket and the fact that this socket has no electricity should be hidden from the light bulb and from the person screwing in the light bulb. According to the 2000 revision of the Declaration of Helsinki, paragraph 29, the use of placebo sockets is acceptable where no proven prophylactic, diagnostic, or therapeutic socket exists.

A systematic review of all previous research into light bulbs must be presented so that the IRB can determine, per 45 CFR 46.11(a)(2), that the risks to the light bulb are reasonable in relation to anticipated benefits. The IRB should also insure that the selection of light bulbs is equitable [45 CFR 46.11(a)(3)]. If the light bulb has less than 18 watts of power, then additional requirements (45 CFR 46.401 through 409) apply.

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:

- New IRB Updates page
- New Common Issues page
- Resources and guidance for Researchers page updated and re-organized
- Landing page updated with new links and the new main phone number and general email address for the IRB office
- Newsletter page updated to indicate topics included in each issue to make browsing old issues easier
- Added forms for human subjects research determination requests

New forms added to the library:

- Human Subjects Research Determination form
- Humanitarian Use Device (HUD) continuing review form
- Revised form to request waiver of assent/consent
- Revised consent template – minor revisions regarding assent signature section

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