Human Research Newsletter

JANUARY 31, 2018 VOLUME 4, NUMBER 1

INSIDE THIS ISSUE:

Congratulations to Lori Roesch!

Lori Roesch, Research Integrity Manager was named a Co-Chair of the Council for Certification of IRB Professionals (CCIP) during the annual PRIM&R* meeting in November of this past year.

This council oversees the certification process for those seeking the CIP certification. CIP certification stands for Certified IRB Professional. To earn this certification candidates must be eligible to take and pass a rigorous examination developed by the Council for Certification of IRB Professionals (CCIP) with substantial input from leading members of the HRPP/IRB community. Candidates are tested on the common body of knowledge relevant to all IRBs, including those overseeing behavioral and biomedical research, to ensure that credential holders are trained to use their skills in a variety of IRB environments.
*Public Responsibility in Medicine and Research

Delay in the Implementation of the 2018 Common Rule

The revisions to the Common Rule (Human Subject Research regulations) were scheduled to go into effect on January 19, 2018. On January 17, 2018 the Department of Health and Human Services announced that the implementation date has been delayed by 6 months until July.

There is now an open comment period through March 19, 2018. The notice in the Federal Register (published 01/22/2018) can be viewed here: https://www.gpo.gov/fdsys/pkg/FR-2018-01-22/pdf/2018-00997.pdf.

To submit comments during the open comment period or browse posted comments, go here: https://www.regulations.gov/document?D=HHS-OPHS-2017-0001-0001.

CITI program support

Continuing Review Submission Deadline

The IRB office has been receiving numerous late submissions for annual continuing reviews. We wanted to remind teams of the expectation that the Continuing Review submissions are submitted **no later than 60 days** before the expiration date. This deadline is noted in the automatic reminders about upcoming CRs, although you will have to calculate the specific date. As a courtesy, Lori is personally contacting PIs with past-due submissions, but this may be discontinued in the future and the study allowed to lapse.

CITI Training Requirements – Study Staff from Other Institutions

Recently the IRB office has received a lot of questions about what training is required when staff are being added to the study team who are from other institutions and have already completed CITI training for a different institution. "Do they also have to complete the MCW/CHW CITI training course?"

If an individual from another institution is otherwise engaged in research at CHW, but all of that individual's research activities are taking place at the collaborating institution, we will accept their home institution's training requirements.

Those who are conducting research activities and who CHW requires to be current with and take the MCW/CHW CITI training (even if completed CITI at another institution):

- Individuals leaving a former institution hired on as new staff at MCW/CHW
- Collaborating individuals from outside institutions who will be conducting research activities within CHW/MCW

However, if any of the modules completed at another institution are the same as those required by the MCW/CHW course, these do not need to be taken again and would be credited when the individual associates their profile with MCW.

Caveat: CITI determines whether a particular module completed at another institution can be credited by the module ID number. The ID # of the MCW module and the module taken elsewhere need to match. Sometimes, the module title will be identical, but the module may have been revised or changed by CITI so it is given a new ID # and is considered a different module. Additionally there is a "look back" of 3 years on some of the courses. In these cases, if the course was completed someplace else more than 3 years ago, the system will not give credit for completion. The result is that while some of the modules

completed elsewhere will be given credit when taking the MCW course, some users may have more to do than others depending on these factors**.** However, it is still expected that anyone listed on the study team completes the MCW CITI course appropriate to the study.

To ensure credit for modules already completed at different institution, staff need to do the following:

1. Log into CITI using the SAME account as the one used at another institution (do not create a brand new account)
2. From the main menu, choose "affiliate with another institution" and affiliate with the Medical College of Wisconsin
3. From the menu item "Medical College of Wisconsin Courses" in the main menu, select "add a course"
4. Select whichever course most closely matches the type of research in which are participating
5. Any identical modules completed at another institution will show up in the MCW course as being complete.
6. Users only have to complete those modules under the MCW course that show as incomplete to satisfy the CITI training requirement. How many modules this will entail depends on how many are duplicates of those completed through another institution's course – each institution selects their own combination of modules for a particular course.

When a staff addition is being reviewed, IRB analysts will look for completion of CITI training and this must be done before they can be added to the study.

Resources for more details on Certificates of Confidentiality and the NIH revised policy:

General information
Suggested consent language

NEW Research Protected by Certificates of Confidentiality per the Revised NIH Policy – Modification to your Research May be Needed

In the July 13, 2017 issue we included information about Certificates of Confidentiality (CoC)

In the October 3, 2017 issue we provided information about the revised NIH policy regarding Certificates of Confidentiality.

We are now asking investigators to take a look at their ongoing research to determine if it is automatically covered by a CoC. As a brief reminder, effective October 1, 2017, CoCs will be issued automatically for any NIH-funded project using identifiable, sensitive information that was on-going on/after **December 13, 2016.**

- The CoC will be issued as a term and condition of award

- There will be no physical certificate issued

Impact to Investigators:
This change in NIH's policy will apply to NIH-funded research in which identifiable, sensitive information is collected or used, including research that:

- Meets the definition of human subjects research, including exempt research in which subjects can be identified
- Is collecting or using human bio-specimens that are identifiable or that have a risk of being identifiable
- Involves the generation of individual level human genomic data
- Involves any other information that might identify a person

If your research meets any of the above criteria then your research data or information is automatically protected by a CoC from NIH, **even if this was not requested by the investigator.** This may leave some research consents lacking the required language about Certificates of Confidentiality. We have updated the Summary form, Amendment form and the Continuing Review form with a question addressing this issue as another reminder to think about this and update the consents as needed.

In response to this change in NIH policy and in alignment with MCW's approach, the CHW IRB requires all CHW IRB approved research projects now protected by a CoC from NIH to submit an amendment , if needed, to revise their consent form(s) to include the NIH recommended language into the consent form(s) no later than May 1, 2018

If you have any questions, please feel free to contact the CHW IRB Office, CHWIRB@chw.org.

What Documents Should I Submit?

The IRB office is working on creating updated submission checklists for study teams to use as reference regarding what to include in various submissions. In the meantime, we wanted to call out two particular issues.

Continuing Progress Reports:

OHRP Continuing Review Guidance

Regulations require the IRB to conduct continuing review of research at least annually. This review is a re-assessment of the **totality** of the project, and all activity over the past year, to be sure that the regulatory criteria for approval are still met.

In evaluating our current practice it was identified that this was not always practiced consistently. Therefore, going forward it is expected that **all** of the **currently approved** documents still relevant to the ongoing conduct of the study will be included in

the continuing review package (for example, if the study is closed to enrollment we would not expect to see a consent document.) This is to provide the IRB members with all relevant information for their review and re-assessment. This includes any interim publications/findings, subject-facing documents, and a summary of non-compliance or problems that have occurred since the last continuing review report. There should **not** be any **revised** documents submitted with the continuing review.

Modifications to a project:

When submitting an amendment, the only documents that should be submitted are those documents that required revisions due to the modification. If all documents (even those with no changes) are submitted, the IRB must review them. Thus, in the interest of efficiency, we will only accept those documents have been changed due to the modification.

Submitting tracked v. clean versions, as of 02-01-2018:
Any revised documents that are **locally** created and controlled:

- **Revised documents:** Submit only a Word version with ***changes tracked*** (use the tracking function in Word rather than highlighting or underlining changed sections)
- **New documents:** submit only a clean Word version
- Prior to stamping, after changes are finalized and approved, the IRB office will accept the changes to create a clean version of the document.
- A clean, unstamped word version (for use by study teams as a base for future modifications) of any written materials to be given to subjects will be published in the board documents section of IRBNet.
- A stamped PDF version of any written material to be given to subjects will be published in the board documents section
- ***Examples***: Consent/Assent documents, HIPAA documents, CHW summary document, locally created ads and recruitment material, locally created patient information sheets, diaries, instructions, etc.

Any documents that are created and controlled by an **external sponsor:**

- Submit **both** a tracked version and a clean version of all documents that have been revised.
- If a sponsor provides a "summary of changes" with sufficient detail (table of each section changed with both the old language and the revised language) this can be substituted for a sponsor's tracked version.

New Process to Request a Temporary Change in PI

In a previous newsletter, we discussed the importance of having a temporary PI assigned to assume responsibility for the conduct of a research study when the original PI has a long-term absence, either planned or unplanned.

When a PI will be absent for 30 days or longer, we have altered our process to avoid the need to submit a full staff change amendment. This should ease the burden on both study teams and the IRB staff and allow this important change to be acknowledged quickly.

A new form is available in IRBNet and on the HRPP website at https://connect.chw.org/departments-services/clinical-departments/childrens-research-institute/human-research-protection/Forms

In summary:

1. The only document that needs to be submitted is the form: *Request for Temporary Change of Principal Investigator*
2. This should be submitted as an "Other" package
3. Any documents that have the name of the PI who will be temporarily absent do NOT have to be updated and included. If the change becomes PERMANENT, then a regular AM will be required with the documents updated.
4. These will be tagged for the Research Integrity Manager and Research Quality and Education Specialist who will review and acknowledge as an administrative review which can be done quickly.
5. This form is intended for use when the absence will be **30 days or longer.** For shorter absences the IRB does not need notification, but it is expected that one of the following is done:
    a. Study activities cease until the PI returns
    b. Oversight of study activities is delegated to an **appropriately qualified** member of the study team (such as another investigator)
    c. The PI continues to assume PI responsibilities remotely if it is safe and appropriate to do so.

More details and instructions are available on the form. Study teams can begin using this immediately.

Please do not hesitate to contact the IRB office with questions or concerns at 414-337-7133 or chwirb@chw.org

IRB Reliance Takes Time, Even if they are "SMART"

Common Misconception: "It's Just a Piece of Paper"

A common misconception among research teams is that establishing a single IRB of record for review of multi-site human subject research will be quicker than utilizing each site's local IRB. Often times, it takes longer to establish a single IRB because an agreement needs to be entered into and followed carefully (called an IRB reliance agreement.) Reliance agreements can be for a single study, multiple studies already in the works, or can be an agreement to work together on all or some future projects that have yet to be finalized (master agreement). The decision to enter into a reliance agreement involves IRB representatives from each site, often involves legal teams from each site, may involve other institutional representatives depending one each site's processes, and must be signed by each site's Institutional Official. Often there are multiple documents sent back and forth until final versions are acceptable to all parties.

Some organizations or research consortiums choose to enter into a master reliance agreement to avoid having to begin with a new reliance agreement each time a new protocol being. SEWIC (Southeastern Wisconsin IRB Consortium) is an example of this type of arrangement and includes: MCW, CHW, UWM, MU, MSOE, FH and BCW If a master reliance agreement is already in place, the process can be quicker, but each site still needs to consider details of each protocol to ensure that relying on the other site is appropriate. Things considered include, but are not limited to: the other IRB's experience with the type of subjects involved (i.e. children, prisoners), experience with a certain type of procedure or drug, accreditation status, and resources available for review.

Common Misconception: "SMART IRB Will Solve Everything"

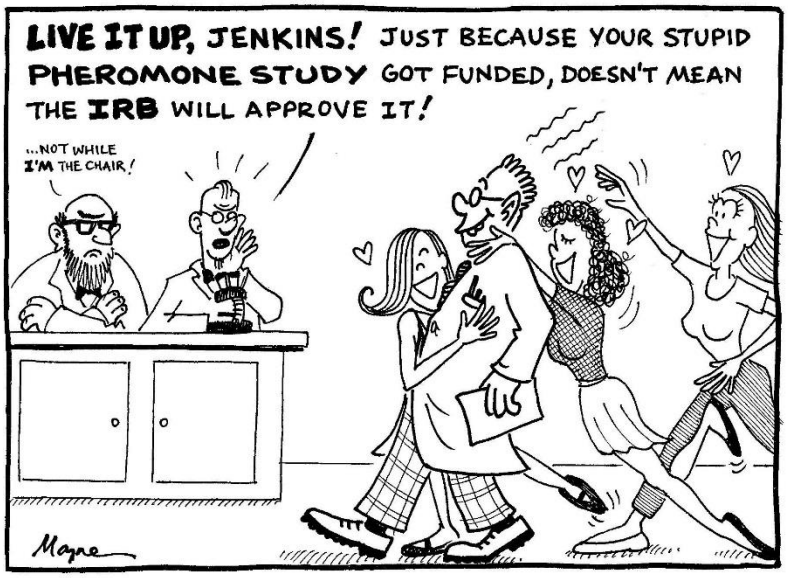
With the arrival of the SMART IRB platform for multi-site research, a lot of research teams are asking "when can we begin to use this at our site?" The answer is, we do not have a firm date, but we have signed the master agreement and have begun developing processes and establishing expectations when using this platform. The beauty of the SMART IRB setup is that there is already a master agreement in place; however, each site may choose to have specific reliance agreements for particular protocols in addition. In talking with other sites, use of SMART IRB is varied, even for sites that have been involved for some time. Many sites are still using forms and templates from outside the SMART IRB system and often communicating outside the system as well.

Truth: You Can Help Us!

First, plan ahead and discuss with us early. Also, please be patient with the reliance process and provide as much information as possible on all forms requested. In your IRBNet submissions, be certain to explain exactly what activities occur where and who performs them. The more information you can provide up front, the better. Any time activities occur outside of CHW or collaborators from outside CHW are considered (including those activities that occur in MCW/BCW/FH space) please let us know. Feel free to contact CHWIRBReliance@chw.org to alert us to the potential need for a reliance agreement and for questions.

Our office is developing special expertise to process these requests, and specific processes and flows so we can be consistent and efficient in our review. This is happening in IRB offices all over the country. We are not alone.

Thanks for your understanding, patience and support as we work through this!



International Compilation of Human Research Standards – 2018 Version Now Available

The 2018 edition of the International Compilation of Human Research Standards has been released and is now available on-line: http://www.hhs.gov/ohrp/international/compilation-human-research-standards/index.html.

The Compilation features listings of over 1,000 laws, regulations, and guidelines on human subject protections in 130 countries, as

well as standards issued by a number of international and regional organizations.

The updated edition includes hundreds of updates from the previous year.

Four new countries are included in the 2018 edition: Algeria, Madagascar, Mali, and Saint Lucia. For the first time, this year's compilation includes a section on Social-Behavioral Research.

The listings are organized into nine categories:

1. General Research
2. Drugs and Devices
3. Clinical Trial Registries
4. Research Injury
5. Social-Behavioral Research
6. Privacy/Data Protection
7. Human Biological Materials
8. Genetic Research
9. Embryos, Stem Cells, and Cloning

Most of the listings include a hyperlink that allows the user to directly access the law, regulation, or guideline of interest.

UPDATES, REMINDERS AND TIPS

- If your research involves survey questions that may indicate a concern about a subject harming themselves or others, there MUST be a detailed plan and explanation of resources available described in the protocol and a brief explanation in the consent form addressing answers that indicate a subject may be at risk.

- When amending a project to remove study staff, don't forget to also remove their access to the project ('unshare') in IRBNet. Contact the IRB office for instructions on how to do this if needed.

- If the IRB staff has unlocked a package to request specific changes or items during pre-review, or the study team requested the package be unlocked to make a specific update, please do not make other changes. This will affect the integrity of the package and delay IRB approval.

Reminder and Clarification Regarding Document Footers

Several months ago we alerted the research community to the CHW IRB position about the use of headers and footers. This is to remind study teams about how to use footers and tracking information in consent forms.

There should not be anything in the footer of a document except for:

- Page number
- HIM consent form barcode (or sticker)
- An internal document tracking version number or date (more on this below)

The IRB stamp will be affixed to the bottom left hand side of the document, so this area of the footer should be completely clear so as not to interfere with the stamping.

Some additional clarifications:

- **Protocol** version dates and numbers should not be listed anywhere on the documents except the protocol. When other study documents are tracked using the protocol version information, this creates inefficient and unnecessary review because a protocol version may change without affecting the content of some or all of the documents. Yet, the documents must be updated with the new protocol version information. This then requires they be submitted with the modification and the IRB has an obligation to review all documents in their entirety even though the content has not actually changed.
- A **document** tracking version number or date is acceptable as this will only change if the document itself is revised, which will warrant IRB review of the document changes. This number or date should relate to the version of the **specific** document on which it is printed. This should also be placed in a way that will not interfere with the stamp.
- Sometimes teams include tracking information on the HIPAA form to tie it a particular protocol version or a particular version of a consent form. For example, the HIPAA form may reference the consent form for a particular cohort or phase of the study, or to a specific consent version date.

  To clarify, the HIPAA form goes with the PI as an authorization to release information for that **study** as a whole. It does not matter which consent is being used – the same HIPAA form is signed. So ICF identification on the HIPAA forms is not necessary. The study title is on the form and there should be an IRB effective date stamped on it which indicates that the HIPAA form is current. Therefore, HIPAA forms should NOT include the consent version name or ICF document version or date. If a document or version date will be included, it should be the version of the HIPAA form itself –not ICFs or protocol.

  Additionally, HIPAA forms do NOT need to be submitted every time the protocol or the ICF forms are updated. They only require re-review or re-stamp if something on the HIPAA form changes (PI name or any of the entities listed to whom PHI will be released) AND at the time of continuing review.

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

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 2 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***: New Location…Center 4 South, Main Hospital***

Upcoming sessions:

- **Tuesday February 6th**, **2018 at 2 p.m.** – Certificates of Confidentiality, Overview and Update
- **Thursday February 22**, **2018 at 10 a.m.** – Update on Budgets and Study Feasibility
- **Tuesday March 6, 2018 at 2 p.m. –** Update on Budgets and Study Feasibility
- **Thursday March 22, 2018 at 10 a.m. –** Update on the 2018 Common Rule/ open forum

CRI Quarterly Education Session – February 27, 2018

The first 2018 education session will be a "Town Hall: State of the CRI" to provide the research community with updates from Children's.

Please forward your questions or concerns to Jeff Crawford at JCrawford@chw.org in preparation for the session on February 27th.

This will be held in the Children's Hospital Auditorium from 8:30am to 9:45am.

Pediatric TRU Updates

The Pediatric TRU has moved! If you didn't have the opportunity to stop by the Pediatric Translational Research Unit's recent Open House, please feel free to stop by any time to tour our new space and learn more about the amazing research support we have to offer your team. The TRU is now located on Center 4 South near the "S" Elevators. Please contact Beth Gissibl, TRU Manager @ 266-3994 or Jeff Crawford, TRU Research Coordinator @ 266-7254 for more information.

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 ALWAYS go to IRBNet and select the documents posted when preparing a new submission.

Forms posted:

- New form to request a temporary change of PI
- Updated reportable events log
- New form to request deferral to the NCI CIRB
- Corrected form requesting permission to contact regarding research
- Updated Amendment form
- Updated Continuing review form
- Update CHW Summary form
- New index for HRPP newsletter issues by topic

Would you like to know when the website is updated?

Email Michelle at MMartin@chw.org and ask her to add you to the distribution list alerting staff of web updates.

Questions / Comments / Concerns / Suggestions:

We welcome your feedback. Feel free to bring forward any concerns or suggestions regarding the CHW HRPP or IRB review process to Lori Roesch, CIM, CIP at lroesch@chw.org.

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

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