Human Research Newsletter

OCTOBER 3, 2017 VOLUME 3, NUMBER 4

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Welcome! New IRB Staff - Sue Ahlf

Sue Ahlf joined the IRB staff as an IRB Analyst on October 2, 2017. Sue recently retired from the Clement J. Zablocki VA Medical Center where she served our Veterans for 33 years. Sue began her career as a research technician and most recently held the position of IACUC and Safety Committee administrator, occasionally providing back up coverage for the IRB administrator. In her free time, Sue enjoys cooking gourmet meals and spending time with her family. Sue's extensive knowledge applying research regulations and her customer service approach will be a great addition to our HRPP team at CHW. Please join us in welcoming Sue.

Certificates of Confidentiality (CoC)– Revised NIH Policy

Last issue we provided information about Certificates of Confidentiality issued by the NIH. Since then, the NIH as revised their policy, effective October 2017, which has some significant changes.

The policy, which applies to NIH-funded research, was updated as a result of the need to implement Section 20112 of the 21st Century Cures Act, P.L. 114-255 which states the Secretary of HHS shall issue Certificates of Confidentiality to persons engaged in biomedical, behavioral, clinical or other research, in which identifiable, sensitive information is collected.

As a reminder, these certificates are issued to help protect the privacy of research participants when there is sensitive information collected as part of the research. In the past, NIH issued CoCs, upon request, to researchers to protect researchers and institutions from being compelled to disclose information in response to legal demands that would identify research subjects.

Changes with the new policy:

- NIH funded researchers will no longer have to request a CoC, they will be automatically issued for appropriate research
- NIH funded researchers will not receive an actual certificate for those issued automatically

For more information about NIH CoCs, or to apply for a CoC for non-HHS, non-Federal funded research:

https://humansubjects.nih.gov/coc/index

- Applies to all biomedical, behavioral, clinical or other research funded wholly or in part by the NIH, whether supported through grants, cooperative agreements, contracts, other transaction awards, or conducted by the NIH Intramural Research Program, that collected or uses identifiable, sensitive information
- This policy will be included in the NIG Grants Policy statement as a standard term and condition of award effective October 1, 2017 for new and non-competing awards
- All research commenced or ongoing on or after December 13, 2016 and is within the scope of this policy is issued a CoC through this policy
- Under the new policy, disclosure is not up to the discretion of the investigator. Disclosure is only permitted in the following circumstances:
  - If required by other Federal, State or local laws, such as reporting for communicable diseases
  - If the subject consents to the disclosure
  - For the purposes of scientific research that is compliant with human subject regulations
- The restrictions on disclosures apply to all researchers or research institutions previously issued a CoC who are engaged in research.

If an investigator has non-Federal funding, and a CoC is desired due to the nature of the data, these can still be requested through the existing online CoC application system. Typically, for sponsored or cooperative research the sponsor will apply for the CoC. However, an investigator can also apply for non-Federally funded investigator initiated projects.

To determine if the policy applies to research conducted or supported by NIH, investigators will need to ask and answer the following questions:

- Is the activity biomedical, behavioral, clinical or other research? If the answer is “no”, the activity is not issued a CoC. If the answer is “yes” the investigator needs to answer the following, additional questions:
- Does the research involve human subjects as defined by 45 CFR part 46?
- Are you collecting or using biospecimens that are identifiable to an individual as part of the research?
- If collecting or using biospecimens as part of the research, is there a small risk that some combination of the biospecimen, a request for the biospecimen, and other available data sources could be used to deduce the identity of an individual?
- Does the research involve the generation of individual level human genomic data?

If the any to any of these is “yes” then this policy will apply to the research.

CHW IRB Position Statements

As part of our ongoing effort to provide clarity and improve quality and consistency, we will start issuing CHW IRB position statements on various topics. There are instances when a policy is either silent on an issue, or has not yet been updated to reflect current

practice and thinking. To help clarify things, and provide documentation as needed for sponsors, etc. we will be creating and publishing position statements, when needed, to describe the CHW IRB's thinking on a topic and current process or documentation requirements.

Currently there are two position statements available here:

https://connect.chw.org/departments-services/clinical-departments/childrens-research-institute/human-research-protection/position-statements

- Use of the footer in the IRB consent documents for department or sponsor tracking information
- Submission of documents for stamping

If you have other topics you think may benefit from a position statement, please send us your suggestions for consideration.

Who can serve as the PI at CHW?

As the research community knows by now, the CHW IRB is in the process of making a great deal of revisions to process, forms, and policies. Often, we will implement an operational change prior to the final update of the policy. In this case, we have made the decision that fellows and residents may be listed as an investigator, but that an attending must be listed as the PI.

We are moving away from allowing co-Principal Investigators for a study. The PI is the individual ultimately responsible for the conduct of a study. When there is more than one PI listed, this can cause confusion as to with whom the ultimate authority and accountability lies. So, we are limiting the PIs for a given project to one. Other individuals to whom responsibilities are delegated should be included as investigators or key personnel.

Additionally, the CHW IRB will not accept students/residents/fellows, or non CHW/MCW faculty or permanent staff to serve as PIs. We frequently encounter issues when a student, resident or fellow or non-CHW/MCW individual is listed as the PI. Then the project comes to its annual review date, no CR is submitted, and the PI has left the institution without closing the project or transferring the project to another PI. Often, the IRB manager is unable to track down that PI, and needs to find someone who can submit an amendment to update the PI, and then submit the CR. The project becomes in danger of lapsing which is considered non-compliance.

As a reminder, those who can serve as a Principal Investigator are limited to the following:

- CHW Medical/Dental staff member in good standing

- CHW employee, or CRI Investigator.
- Students, residents, and fellows must have a CHW medical/dental staff member, CHHS employee, or CRI Investigator listed as the principal investigator on the study team.
- If a study requires patient care tests, procedures or medications and is conducted at a CHW site, a member of the Medical/Dental Staff or employee of CHW must serve as a principal investigator for the study.
- *Non-Medical/Dental staff members,* who are approved by Children's Research Institute, may independently serve as a principal investigator on studies that do not involve medical or surgical tests, procedures or medications.

Deferrals and Reliance Agreements

In reviewing projects that have multiple institutions involved and requests to rely on outside IRBs, the CHW IRB office has determined that there are key questions that need to be answered up front. We have created an addendum to a form already in use. For those familiar with projects involving MCW, BCW, FH, Marquette University, MSOE, or UW-Milwaukee (SEWIC sites), this form will look quite familiar. For those unfamiliar with this form, this is a heads-up that it will become a staple in our processes.

Currently, the first four pages of the Investigator Reliance Request form are used for any SEWIC requests, and CHW IRB has not changed any aspect of these pages (because we alone do not control them). The last page is new and MUST be filled out any time CHW is involved. If you submit the first four pages, we will now require you to also fill out the last page, regardless of which site you first submit to. The first section must be filled out for ALL CHW requests. The second section only needs to be filled out if your team is requesting CHW IRB rely on an IRB outside of SEWIC. You do not need to go back to those forms already submitted and fill out this addendum, unless it is specifically requested on a protocol-specific basis by IRB staff.

Depending on the answers to all questions on this form, more information and/or paperwork may be required to answer all pertinent questions.

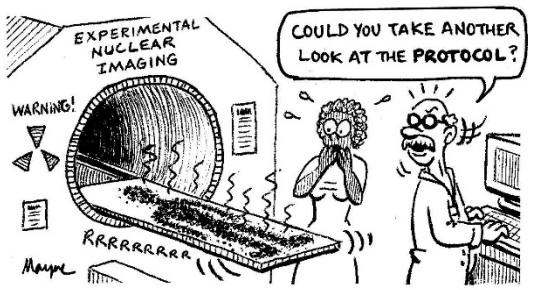
Please understand that while this change will create a little extra work up front, it should help prevent problems and delays in processing your reliance requests. Thank you for your continued patience with our highly-evolving department and for extra efforts!!

Please email chwirbreliance@chw.org if you have any questions about this process or how to fill out this form.

Education Opportunities

Reportable Event – New Form and Process

The process and form for reporting to the CHW IRB has undergone significant changes (improvement.) We are offering several sessions throughout October for research staff to come and review the form with us, ask questions, and become familiar with the new form, guidance and process. These sessions are all the same, hopefully there is one that will work with your schedule.



Day	Date	Time	Room
Tuesday	10/10/17	2pm-3pm	TRU Conference Room
Wednesday	10/11/17	11pm-1pm	Children's Clinics Building, Lobby Conference Room
Friday	10/13/17	1pm-3pm	Children's Corporate Center, Room 255
Monday	10/16/17	9am-11am	Children's Clinics Building, Lobby Conference Room
Tuesday	10/17/17	12pm-2pm	Children's Corporate Center, Room 255
Tuesday	10/24/17	9am-11am	Children's Clinics Building, Lobby Conference Room
Thursday	10/26/17	10am-11am	TRU Conference Room
Friday	10/27/17	12pm-2pm	Children's Corporate Center, Room 255

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 topics are to be determined, but check back at the website for more information, as well as 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.

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

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
414-337-7133
CHWIRB@chw.org

We're on the Web!

https://connect.chw.org/hrpp

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

- **Tuesday October 10**, 2017 at 2 p.m. – Reportable events
- **Thursday October 26**, 2017 at 10 a.m. – Reportable events
- **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

Pediatric TRU Updates

The Pediatric Translational Research Unit is on the move!
We will be moving into our newly remodeled space on **C4S** in early-mid December.

Our move will require us to close for one day – more info to come once a date has been selected. Also, please be on the lookout for our ***open house*** to see our new space!

Any questions – contact Beth Gissibl TRU Manager or Jeff Crawford TRU CRC

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. If an outdated form is used, you may be asked to resubmit using the current form.

Website content added or updated:

- Updated IRB Roster
- 2018 CHW IRB Meeting schedule
- FAQ page
- Forms page
- Position Statement page

New or updated forms added to the IRBNet library and Website:

- Reportable Events/New Information form
- Reportable Events/New Information – Guidance on Reporting to the CHW IRB
- Reliance Request form with CHW addendum

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