Children's Hospital of Wisconsin

Human Research Newsletter

JANUARY 30, 2017 VOLUME 3, NUMBER 1

INSIDE THIS ISSUE:

Welcome New IRB Office Staff!

Cassandra Baumgart – IRB Coordinator

Cassandra Baumgart, MS, MLS (ASCP), CCRP started with us on November 14th, 2016. She has an educational background in Clinical Laboratory Science and Biochemistry and recently earned a Master's degree in Leadership, and is a Certified Clinical Research Professional. Cassandra lives in Green Bay and will be working remotely most of the time, but traveling to CHW on IRB meeting days. She will be working with both IRBs. We are very happy to have Cassandra join us and provide her valuable experience.

Lori Roesch – Research Integrity Manager

Please join us in welcoming Lori Roesch to Children's in her new role as Research Integrity Manager effective Jan 30th. Lori will be partnering with Children's IRB Chairs and the staff of the IRB Office to ensure safe and compliant conduct of clinical research at Children's. Lori has extensive experience in human subject research protections, most recently at Zablocki VA Medical Center and previously at Aurora Health Care. In addition, she serves as a site visitor and reviewer for sites considering accreditation through AAHRPP (Association for the Accreditation of Human Research Protection Programs). We're so excited for Lori to join our team and look forward to working with her!

A Message from Elizabeth Bedwell, Vice President – Research Administration

Thank you again for your patience over the past few months as we have been working through a review backlog following some staff vacancies. Additional staff members are making great progress with on-boarding, and time to review has decreased substantially. Thank you for your cooperation and close communication with the IRB office staff!

Again, we do appreciate your partnership on this as we strive to be both compliant with regulations and timely. Please do not hesitate to contact Elizabeth Bedwell (ebedwell@chw.org) if you have any specific concerns you would like to discuss.

Resources for more details on the revisions to the Common Rule:

- Full text of the Final Rule
- OHRP Press Release regarding the Final Rule
- WIRB Webinar "Understanding the Final Common Rule"
- WIRB PowerPoint "Understanding the Final Common Rule"
- Kinetiq Summary of Final Changes to the Common Rule

Revisions to the Common Rule Have Been Finalized

On January 18, 2017 the Department of Health and Human Services (HHS) through the Office of Human Research and Protection (OHRP) issued final regulations (the Final Rule) implementing changes to the Federal Policy for the Protection of Human Subjects (the Common Rule).

These revisions were proposed in September of 2015 and published in the Federal Register for public comment through the Notice of Proposed Rulemaking (NPRM). In response to concerns raised in the public comments and review process, the final rule was modified and contains a number of changes compared to the original proposal. Some provisions were adopted, some modified, and some were eliminated.

Research teams will have many questions on what this means for their work. However, the changes to the research community's day to day work will not happen immediately, and for now research teams should continue to do things as they have been. The effect of these changes will be gradual over the next year.

- Even though the regulations have been finalized, there is still the possibility that the new administration could overturn this. This will be monitored, but for now, the focus will be on familiarizing ourselves on the changes without making immediate drastic changes in our process.
- The date for being compliant with these new regulations is a year away on January 19, 2018 (three years for the single IRB requirement on January 20, 2020.)
- There is the need for thorough review and discussion at the IRB and with institutional leaders to become familiar with the changes, and there will be decisions needed regarding details of how this will be implemented at CHW.
- There will be a lot of revisions to policies, changes in processes, updates to templates etc.

All of this takes time, and will be communicated to the research community in a variety of ways. We will be providing opportunities for education on the new Common Rule and how this will impact the work of research teams as well as IRB members. We anticipate there will be a vast amount of information, guidance documents, and training opportunities being released from a variety of groups over the coming months. We will provide information on these as we learn of them.

As always, don't hesitate to contact the IRB office with questions or to request assistance or information.

Very generally, the summary of revisions:

- Required additional content in informed consent documents
- Required use of a single IRB for most multi-institution research studies
- New options for the use of "broad consent" documents for research involving identifiable data or identifiable biospecimens
- New categories of "exempt" research
- Elimination of continuing review requirements for certain

human research studies
- Required posting of consent documents for certain federally-funded trials to a public website
- Elimination of grant congruency review by the IRB
- New criteria for limited IRB review required for certain exempt categories

Proposed changes not incorporated into the Final Rule:
- The definition of 'human subject' to include non-identifiable biospecimens, as well as most of the proposed changes to biospecimen research requirements
- Use of federally-developed templates for "broad consent" forms and decision tools for making exemption determinations will not be implemented
- The proposal that non-federally funded clinical trials be subject to the revised Common Rule
- The "excluded" categories of research
- The requirement for standardized privacy safeguards for identifiable private information and identifiable biospecimens

Clinical Trials Registration and Results Information Submission

In September, the National Institutes of Health, Department of Health and Human Services issued a final rule detailing the requirements for submitting registration and summary results information, including adverse event information, to *ClinicalTrials.gov.*

This rule is an effort to make information about clinical trials widely available to the public and to improve peoples' ability to find clinical trials and access investigational therapies. This rule expands the legal requirements for submitting registration and results information for clinical trials involving U.S. Food and Drug Administration-regulated drug, biological and device products.

Requirements under the final rule apply to most interventional studies of drug, biological and device products that are regulated by the FDA. The requirements do not apply to phase 1 trials of drug and biological products, or small feasibility studies of device products. The Final Rule specifies how and when information collected in a clinical trial must be submitted to ClinicalTrials.gov. It does not dictate how clinical trials should be designed or conducted, or what data must be collected.

Important elements:

- Providing a checklist for evaluating which clinical trials are subject to the regulations and who is responsible for submitting required information;
- Expanding the scope of trials for which summary results information must be submitted to include trials involving FDA-regulated products that have not yet been approved, licensed, or cleared by the FDA;
- Requiring additional registration and summary results information data elements to be submitted to

For more information on the Final Rule – Clinical Trials Registration and Results Information Submission:
- Full text of the rule
- NIH news release
- Webinars on ClinicalTrials.gov
- NIH policy on the Dissemination of NIH-funded clinical trial information

ClinicalTrials.gov, including the race and ethnicity of trial participants, if collected, and the full protocol;

- Requiring additional types of adverse event information; and

- Providing a list of potential legal consequences for non-compliance

The Final Rule is effective for applications for funding, including grants and contracts submitted on or after January 18, 2017. For the NIH intramural program, the Final Rule applies to clinical trials initiated on or after January 18, 2017. Responsible parties are expected to be in compliance as of April 18, 2017.

Decedent Form for PHI in Research – What is it and When do I Use This?

The Federal Regulations governing human subject protections in research define "human subject" in research as a living individual (45 CFR 46.102(f) and 21 CFR 50.3(g).

However, in addition to the FDA and the OHRP Common Rule, HIPAA has additional rules that must be followed when conducting a research study. Specifically, there are criteria that must be met/followed when using a decedent's PHI for research.

When research is being done with a decedent's information, the HIPAA Privacy Rule at 45 CFR 164.512(i)(1)(iii) requires that the covered entity (CHW via the IRB) obtains from the researcher:

1. Representation that the use or disclosure sought is solely for research on the protected health information of decedents;
2. Documentation, at the request of the covered entity, of the death of such individuals; and
3. Representation that the protected health information for which use or disclosure is sought is necessary for the research purposes.

A **Certification for the Use of PHI of Decedents form** is how the IRB/Privacy Board obtains the required representations and assurance (of providing documentation if requested) from the investigators who may be accessing decedent PHI for their research project.

If an investigator knows that some or all of the data being collected for research will be from deceased individuals, this form is required. Prior to accessing any data of a deceased individual, the research team must submit this form to the IRB office with their project.

In cases where teams may not know if some of the subject population will be deceased, as in retrospective chart reviews for example, this form should be included with the submission to cover this potential situation.

OHRP Launches Public Outreach Website

About Research Participation*-to view go to: www.hhs.gov/about-research-participation.*

OHRP announced the launch of its new public outreach website: About Research Participation. These resources are designed to help potential volunteers better understand research and find the information they need to decide whether to participate in research. Trial coordinators and research staff also could use these materials to facilitate and improve the informed consent process. This project broadens OHRP's educational and outreach efforts to the general public.

The newly developed resources include a series of short videos about participating in research, a printable list of questions that potential volunteers can ask researchers, and links to additional resources. We hope these materials will be a valuable resource for the research community as well as the general public. Please consider sharing this information with other human research protection professionals and programs!

FDA/OHRP Publish Final Guidance on "Use of Electronic Informed Consent in Clinical Investigations – Questions and Answers"

To access the Federal Register notice announcing the availability of the final guidance document go to: https://www.gpo.gov/fdsys/pkg/FR-2016-12-15/pdf/2016-30146.pdf or

https://www.gpo.gov/fdsys/pkg/FR-2016-12-15/html/2016-30146.htm

To access a copy of the final guidance document go to:

https://www.hhs.gov/ohrp/regulations-and-policy/guidance/use-electronic-informed-consent-questions-and-answers/index.html

In December 2016, the Office for Human Research Protections (OHRP) and Food and Drug Administration (FDA) published final guidance aimed at providing answers to commonly asked questions about using electronic systems and processes that may employ multiple electronic media to obtain informed consent for both HHS-regulated human subject research and FDA-regulated clinical investigations of medical products, including human drug and biological products, medical devices, and combinations thereof. This guidance finalizes the draft guidance entitled "Use of Electronic Informed Consent in Clinical Investigations--Questions and Answers" issued in March 2015. The final guidance was developed in collaboration with FDA and OHRP and is issued as a joint final guidance.

UPDATES, REMINDERS AND TIPS

- Last month the IRB underwent a routine audit/inspection by the FDA. We are happy to report this went well and there were no corrective actions needed.
- When submitting a HIPAA waiver form, rather than listing all the staff at CHW who will use and/or receive PHI (**question 4a**), you can reference the registration page. This will save time by preventing the need to update this form every time study staff changes. **Question 4b** will still need to list those outside CHW as this may not be captured in the registration page.
- When sharing projects in IRBNet, the Principal Investigator should always be granted full access to a project. The PI is ultimately responsible for the project, so they should have unrestricted access to review, make changes, and manage their project.

- The IRB office is no longer identifying projects with the CHW number (xx/yy), but only by the IRBNet number. The CHW number was a holdover from the days of submitting and managing everything on paper before we had an electronic submission system. Because IRBNet assigns identifying number to projects, there is no need to retain the CHW number in addition to this.

- When a form or a template is updated this is communicated in the quarterly newsletter, and through an email to the research community. These new versions are also uploaded to IRBNet as soon as they are effective. Our recommendation, in line with general best practices in dealing with documents that get revised, has always been that when a submission is being created study teams should be checking IRBNet to pull the **most current** version of the form or template. If this is done, this should prevent having to redo forms after you have submitted them, even if the form is updated in between formal communications or for some reason a team member missed a communication.

- If an investigator plans to leave MCW, he or she must notify the Office of Research and IRB. Research may either be transferred to another Investigator by submitting an amendment, or closed by submitting a final Continuing Progress Report (CPR). The Agreement of Investigator Responsibilities form should be included with amendment submissions.

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 both 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 sessions:

- **Tuesday February 7,** 2017 at 2 p.m. – Update on the Recent Revisions to the Common Rule (Human Subject Protection Regulations)
- **Thursday February 23**, 2017 at 10 a.m. - Update on the Recent Revisions to the Common Rule (Human Subject Protection Regulations)
- **Tuesday March 7**, 2017 at 2 p.m. – Assent/Parental Permission and 2 parent consent requirements/pediatric risk level)
- **Thursday March 23**, 2017 at 10 a.m. – Assent/Parental Permission and 2 parent consent requirements/pediatric risk level

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

CRI Quarterly Education Session – March 28, 2017

CHW IRB Update - a review of changes and updates over the last year or so such as staff updates, new internal processes, forms updates, etc. as well as a look at future changes and improvements.

Please forward your questions or concerns to Michelle Martin at MMartin@chw.org or Jeff Crawford at JCrawford@chw.org in preparation for the March 28th Quarterly education Session

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

Luminaries Lecture Series – OHRP

The OHRP Division of Education and Development Luminaries Lecture Series, features talks by esteemed individuals with thought-provoking insights on human subjects research protections. The series is intended to be of broad interest to investigators and IRB professionals, as well as anyone involved in human subjects research.

To view the Luminaries Lectures series, visit:
http://www.hhs.gov/ohrp/education-and-outreach/luminaries-lecture-series/index.html

New lectures include:

- Dr. Camille Nebeker on "**Connected and Open Research Ethics: Ethical Research Using Personal Health Data**"
- Dr. Ivor Pritchard considering "**Regulating Social Media and Internet Research: Public, Private, or What?**"
- Mr. Mark Barnes discussing "**Return of Research Test Results**"

Pediatric TRU Updates

The Pediatric TRU has some ***exciting*** news! We will be on the move again. Our ever growing and changing environment at Children's will soon be welcoming the Fetal Concerns Center, which is slotted to move to our current space on Center 2. The Pediatric TRU will be moving back to C4SE (Center tower, 4th floor, Southeast Corner of the unit - take the S elevators to the 4th floor and we will be the door on the South end before you cross the skywalk to get to the East tower). This is where we were located before our move to C2, but it will look and feel a lot different due to many revisions that are being made to our new space. In our new department you will notice bigger and better things:

1. Six spacious exam rooms
2. A new and improved laboratory space that will accommodate all current equipment
3. A new and improved waiting room with a wall mounted TV, DVD player, and Wii

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

4. Conference room
5. Four different landing spots for coordinators, research assistants, PI's and Co-I's.
6. A locked entrance to ensure research security with an intercom for patients to get buzzed in

We anticipate that we will move in the second half of 2017, and will communicate specifics as we get closer. The TRU team will be posting updates in our current unit so you can see our new floor plan and other construction updates. We plan to have an open house to show off our new space shortly after settling. If you have any questions, please don't hesitate to reach out!

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 about the final rule
- IRB Review of Research – Does my project need IRB review?

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