April 2022 | Volume 8 | Issue 2

Human Research Newsletter

A quarterly newsletter from
The Children's Wisconsin HRPP/IRB

IN THIS ISSUE

MCW & CW JOINT VENTURE UPDATE-2
CITI TRAINING REMINDER-4
IS MY PROJECT SOCIAL BEHAVIORAL?-4
REPORTABLE EVENT GUIDANCE UPDATE-5
COMPLIANCE CORNER-5
REMINDERS-6
WHAT TYPE OF DATA AM I DEALING WITH?-6
FEEDBACK INFORMATION-8
EDUCATION OPPORTUNITIES-8
ADMINISTRATIVE UPDATES-8

TRANSITION TO MCW PEDIATRIC IRB COMMITTEE - UPDATE

Recently, a communication was sent regarding this transition which stated:

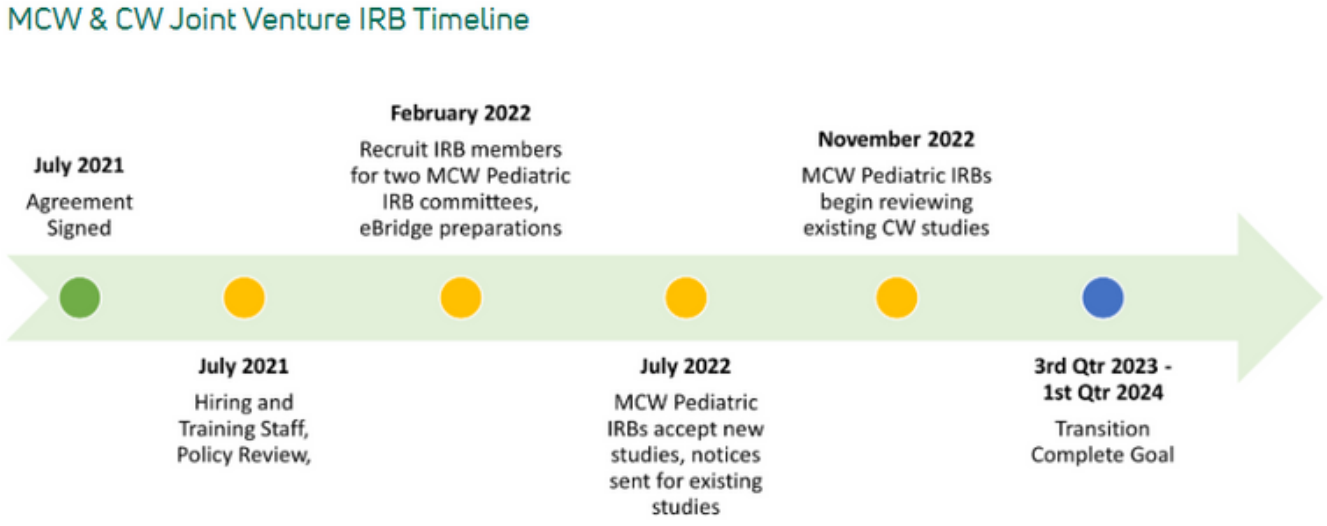
The following update was issued today on Medical College of Wisconsin Infoscope regarding the upcoming research agreement, it can be viewed online at: https://infoscope.mcw.edu/research/News/MCW--Childrens-Wisconsin-Joint-Venture-Research-News.htm

April 15, 2022

IRB Update on the MCW & CW Joint Venture

In July 2021, MCW and Children's Wisconsin (CW) signed an alignment agreement that affects many aspects of their relationship. With this agreement, the newly formed MCW pediatric IRBs will become the IRBs of record for most research conducted at CW. CW will maintain its Human Research Protection Program (HRPP) and have overall responsibility for research conducted in CW space. This transition will be a gradual process, beginning with the review of new studies on July 1, 2022. Existing research studies that were approved by the CW IRB will be transferred to the MCW IRB in groups based upon the date of the next continuing review for each study beginning July 1, 2022.

Currently, we are forming the two new MCW IRB committees that will review pediatric research coming from CW – one minimal risk and one greater than minimal risk. We are identifying IRB committee members and staff to serve on the two new Committees. We are also making changes to the electronic IRB submission system, eBridge, and to policies, procedures, consent and assent forms, and checklists to accommodate CW-specific information and requirements.



Projects that currently are approved by the CW IRB will need to be transferred to MCW IRB oversight. The transfer of these projects will take place over the next year and a half, with invitations beginning on July 1, 2022 for studies expiring in November, coordinated with the expiration date of the research project. The process of transferring currently approved research projects will begin by submitting a 'Transfer Project' application in eBridge no later than 60 days prior to the research project's expiration date. This submission will consist of completing the new research project submission, PRO SmartForm and the Continuing Progress Report (CPR) Smartform. The MCW IRB review will consist of review of both SmartForms and the pertinent historical documentation for the research project since it was initially approved.

This transfer process is dictated by both HHS and FDA, and regulations require that before another IRB accepts oversight of a transferred research project, it should obtain copies of pertinent records (e.g., research protocol, grant proposal, sample consent form, investigator's brochure, minutes of IRB meetings at which the research was reviewed, etc.) to allow it to meet its ongoing review and oversight responsibilities for the research once transferred. The MCW IRB will use CW's IRBNet to access and review these records. This way, investigators and study teams will not have to include copies of all historical documents for submission into the eBridge system. IRBNet will remain the source of this historical documentation.

The MCW IRB and CW HRPP are committed to making the transition process as smooth as possible. Information related to training offerings for CW Investigators and research teams will be made available in April 2022, and will be posted to InfoScope along with the latest news and updates.

Some projects, which have not had any progress in the last few years could be considered for closure. Or, the study may have reached a point at which it can be closed rather than transitioning the project to eBridge and the MCW pediatric IRBs. As a reminder:

Studies that involved identifiable/coded data

- As per the CW data retention policy study data must be retained for a period of 10 years. If this is the ONLY activity that will occur with identifiable/coded data – storage for data retention policy – the study can be closed.
- Data that was previously identifiable/coded should NOT be de-identified for the purpose of closure and continuing analysis after closure due to this data retention policy
- If data collection is complete, there is no further need to access the subject's CW EPIC record to confirm or validate data already collected, and there is no further use/analysis being done on this data – the study can be closed.
- If identifiable/coded data is still being collected, used/analyzed and the EPIC medical record may be accessed for the research, the study should remain open and may need to transition to the MCW pediatric IRB committees.

Studies that involved de-identified data as part of the approved data collection

- If data is still being collected, used, analyzed and the CW EPIC medical record may be accessed for the research, the study should remain open and may need to transition to the MCW pediatric IRB committees
- If data collection is complete and the only study activity left is continued analysis of de-identified data, and the CW EPIC records no longer need to be accessed, the study can be closed.

CITI TRAINING REMINDER

We recently informed the research community conducting research at Children's Wisconsin that the HRPP office would be verifying that appropriate CITI training has been completed by study team members at the time of Continuing Review/Status Report in addition to checking with submission of a new study and staff change amendments. This was communicated in the previous newsletter (January of 2022.)

In general, the user should select the course most appropriate to the research they will be doing. For example, if doing biomedical research this course should be chosen, if doing social/behavioral research then this course should be chosen (see the table in the guidance for more information- link). However, if the individual will potentially be involved in various types of research, either initially or in the future (both biomedical and social/behavioral) then Learner Group 3 should be selected.

The type of training required for a study is not based on each individual's role, rather, it is based off of the type of study. This is valid for the life of the study and does not change based on the status of the study (such as at time of data analysis or after enrollment closes).

Don't forget: GCP training is required when the research is an FDA regulated clinical investigation and/or a clinical trial per HHS (NIH).
It is good practice for the individual submitting the package to verify that all individuals involved in the conduct of the study have appropriate and up to date CITI training completing. https://about.citiprogram.org/

Reliance Questions? You can initiate the Reliance Request Process by visiting our HRPP Connect Page. Look under, "Reliance requests," on our homepage. You can find insight to the reliance process by viewing our flow sheet.

Questions, comments, or suggestions: Your thoughts and recommendations for future newsletter items are much appreciated. Please send your ideas and feedback to Michelle Martin, JD, CIP at mmartin@chw.org.

To register for education sessions, visit our NEW Educational Offerings Connect Page. Space is limited. For more information, visit us on Connect.

Join us for Office Hours! Office Hours are returning every Tuesday from 9:30 - 11:00am via Zoom Contact chwirb@chw.org to sign up.

Office Hours is a chance for study teams to drop-in for general questions and guidance, typically lasting no more than 15 minutes.

Is My Project Social Behavioral Research?

HOW TO DETERMINE

If your project includes a survey or an interview, does that make the project social behavioral research? What about a focus group? Increasingly, researchers are engaging in mixed methods of research involving combinations of different research methodologies from various fields to answer their research questions.

Interviews, surveys, focus groups, and other traditionally social behavioral methods are commonly used in biomedical research. Therefore, it is necessary to consider the aims of your project to determine if it is indeed social behavioral research. Are you using these methods to learn about human social experiences and the way people think and act - like an interview about what it is like to experience the stress of being a parent of a child with a chronic disease? Then you are likely engaged in social behavioral research.

If you employ a survey to ask about the parent's experiences with administering a study drug in a clinical trial and their child's side effects? You are likely using a social behavioral method to learn more in biomedical research. The aims - not the methodology - make research social behavioral.

UPDATE TO REPORTABLE EVENTS GUIDANCE

IND SAFETY REPORTS

During the COVID-19 pandemic, FDA issued guidance entitled "Conduct of Clinical Trials of Medical Products During the COVID-19 Public Health Emergency" which prompted discussion about what types of reports needed to be submitted to local IRBs. We received clarification regarding FDA's position about what needs to be reported promptly to the IRB for any FDA-regulated clinical trial. While recognizing that the 2009 guidance "Adverse Event Reporting to IRBs — Improving Human Subject Protection" remains active, FDA made changes to the IND Safety Reporting Regulations in 2010 and the subsequent 2012 guidance "Guidance for Industry and Investigators – Safety Reporting Requirements for INDs and BA/BE Studies" which states:

Although the rule on IND safety reporting does not directly address safety reporting by investigators to IRBs, questions have arisen about its impact on adverse event reports to IRBs, particularly with respect to the specific adverse events considered to be "unanticipated problems" that must be reported to the IRB. In general, a report that meets the criteria for reporting in an IND safety report should also be considered an "unanticipated problem" and reported to the IRB by the investigator.

FDA's position is that IND Safety Reports submitted to the FDA should also be submitted to IRBs as unanticipated problems noting that the IRB "may decide to take action to safeguard participants that was not taken by the sponsor (e.g., stop administering an investigational drug, revise informed consent form)." Because of the changes made to what must be submitted to the FDA in an IND Safety Report as part of the 2012 guidance, they did not believe that many of these reports will be uninformative.

To that end, we have modified our guidance, form and processes accordingly to capture this information. Please be sure to use our most current form when submitting a reportable event, paying very close attention to SUSARs and IND Safety Reports. Feel to reach out with any questions you may have when considering what to submit and when.

To ensure you're using the most current documents, always access our forms, templates, and documents directly from IRBNet.

COMPLIANCE CORNER

RESEARCH ONLY ORDERS

The process for provider orders for research only orders is the following:

- When a lab or procedure is being done only for research purposes (not clinically required), the provider needs to select "Manual release only" and then select "this procedure is used for research purposes only." This process will prevent the results from being dropped into MyChart.

REMINDERS

TIPS FOR SUCCESS

- When you have several events for the same study that require prompt reporting, these should be submitted as separate report packages/submissions unless it is the same type of event for multiple subjects. Each type of event (unanticipated problems, different types of non-compliance, adverse events, new information) and the circumstances will require individual assessment which could result in potentially different action/follow up and/or determination depending on the individual situation. So while they may all be part of the same study, if promptly reportable, they should each have their own report and analysis submitted in their own package. As always, if there are questions feel free to contact the HRPP office for guidance.

- As part of continuous quality improvement, we frequently review and update guidance documents to provide helpful references for investigators and study teams. These helpful documents can be found in IRBNet and on the HRPP connect pages. We realize that there is frequent turnover and additions to departmental research staff, this is a reminder to consult these guidance documents and direct new staff to the tools for help in answering questions. If further clarification or advice is still needed from the HRPP office, feel free to contact our team at our main email chwirb@chw.org or sign up for a time at office hours on Tuesdays between 9:30 and 11:30 by contacting Kristin Costello at kcostello@chw.org.

- Once the HRPP/IRB has published an IRB-approved consent document in IRBNet, this PDF version must be used for the consent process. To protect the integrity of the document, there must not be any edits to the text or formatting of the published document. A patient label can be affixed to the printed document if available.

WHAT TYPE OF DATA AM I DEALING WITH?

DATA DEFINITIONS

The use of anonymous, de-identified, and coded data are frequently used interchangeably and incorrectly in protocol submissions. It is important to understand the differences between when data is de-identified or identifiable (this includes coded data) as this impacts many facets of conducting research such as:

- Is the project Human Subject Research?
- Can the project be closed while still working with collected data?
- Are collaborators at other institutions "engaged" in the research?

Anonymous:

- Data includes no identifying information because it was never collected or not retained. The data cannot be linked directly or indirectly by anyone to their source.

Identifiable:

- Under the HHS regulations, data is individually identifiable if the identity of the subject is or may be readily ascertained by the investigator or the data includes identifying information. The HHS regulations do not specify what identifies a subject.
- Under the HIPAA privacy rule, data that include health information are individually identifiable if collected or associated a with one or more 18 specific identifiers (name, diagnosis, social security, dates of service, etc.).

The 18 identifiers that make health information PHI are:

1. Names
2. Dates, except year
3. Telephone numbers
4. Geographic data
5. FAX numbers
6. Social Security numbers
7. Email addresses
8. Medical record numbers
9. Account numbers
10. Health plan beneficiary numbers
11. Certificate/license numbers
12. Vehicle identifiers and serial numbers including license plates
13. Web URLs
14. Device identifiers and serial numbers
15. Internet protocol addresses
16. Full face photos and comparable images
17. Biometric identifiers (i.e. retinal scan, fingerprints)
18. Any unique identifying number or code Protected Health information:

De-identified data:

- Under the HHS regulations data are de-identified if all direct personal identifiers are permanently removed from the data or specimens. When data or specimens are de-identified, no code or key is created that would enable the investigator to ever link the data back to the individual.
- Under the HIPAA privacy regulations, data are considered de-identified when all 18 elements that could be used to identify an individual or the individual's relatives, employers, or household members have been removed and the covered entity may have no knowledge that the remaining information could be used alone or in combination with other information to identify the individual

Coded: (Coded is not de-identified)

- Identifying information (such as name or social security number) that would enable the investigator to readily ascertain the identity of the individual to whom the private information or specimens pertain has been replaced with a number, letter, symbol, or combination thereof (i.e., the code); and
- A key to decipher the code exists, enabling linkage of the identifying information to the private information or specimen
- Note that coded information is considered identifiable information and would constitute human subjects research

When is research with data or specimens not human subjects research?

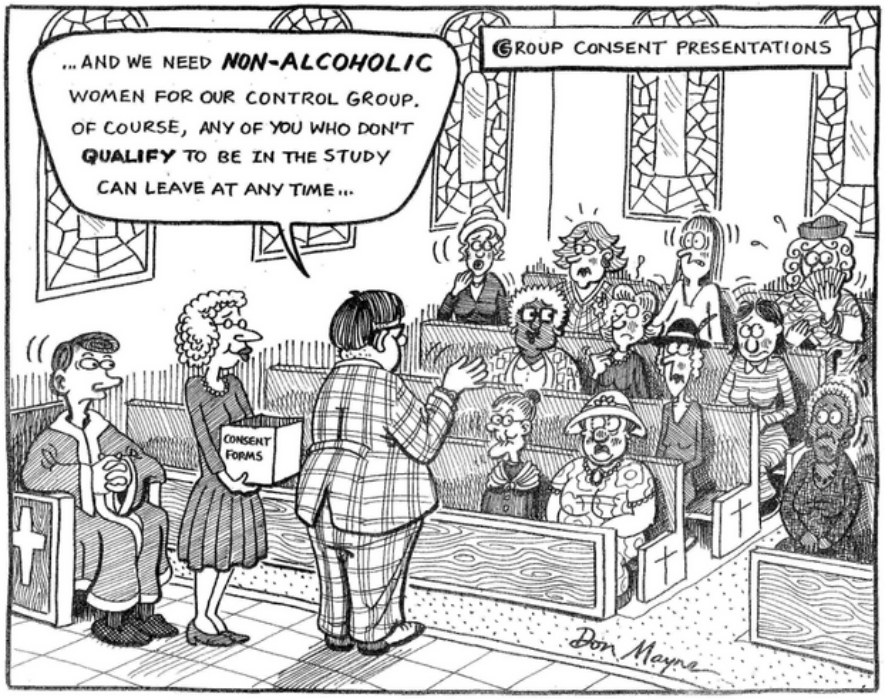
- the private information or specimens were not collected specifically for the currently proposed research project through an interaction or intervention with living individuals; and
- the investigator(s) cannot readily ascertain the identity of the individual(s) to whom the coded private information or specimens pertain because, for example:

  a. the investigators and the holder of the key enter into an agreement prohibiting the release of the key to the investigators under any circumstances, until the individuals are deceased (note that the HHS regulations do not require the IRB to review and approve this agreement);
  b. there are IRB-approved written policies and operating procedures for a repository or data management center that prohibit the release of the key to the investigators under any circumstances, until the individuals are deceased; or
  c. there are other legal requirements prohibiting the release of the key to the investigators, until the individuals are deceased.

For research subject to the HIPAA Privacy Regulations

- Unique identifying numbers, characteristics, or codes must be removed.
- De-identified data may have a re-identification code provided that it is not derived from or related to the information about the individual.
- CW may not use or disclose the code or other means of record identification for any other purpose and may not disclose its method of re-identifying the information.

OHRP (Office of Human Research Protection) Guidances:
Guidance Regarding Methods for De-identification of Protected Health Information in Accordance with the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule
Coded Private Information or Specimens Use in Research, Guidance (2008)



Did you know? In order to maintain hospital accreditation and compliance with The Joint Commission, it is crucial that any skill performed on a Children's patient is only performed by Children's employees or providers who have competencies on file. Skills must be within the individual's professional scope of practice.

HAVE QUESTIONS OR COMMENTS?

HOW TO BEST CONTACT THE HRPP/IRB

Your feedback is welcomed and valued; it is important to us to understand which areas we could improve upon or offer additional educational opportunities. For your convenience, there are a few ways to provide feedback:

• Through our main email inbox at CHWIRB@chw.org
• By phone at 414-337-7133 (available 8:00am-4:30pm, after hours, please leave a message)
• Through our website (Our website offers an opportunity to provide anonymous feedback and your honest opinions are appreciated.)

To allow us to provide responses to your feedback, please use one of these methods. Attempting to communicate with one of our team members directly may cause a delay in response due to the volume of emails received. We look forward to hearing from you!

EDUCATION OPPORTUNITIES

AVAILABLE TO ALL RESEARCH STAFF

Small Group

Join the Children's HRPP/IRB Office and the Pediatric Translational Research Unit (pTRU) Staff for Small Group to discuss select research topics. The same topic will be discussed at both sessions each month. An open forum, you'll have the chance to get your own questions answered, and get help with Epic or IRBNet.

Small Group is held via Zoom. Topics and Zoom call-in information will be included in the Outlook meeting requests. Please feel free contact Jeff Crawford directly at (414) 266-7254 with any questions or to share any suggestions that you may have regarding discussion topics for future sessions.

Quarter 2 Dates

Thurs, May 5, 2022 @ 11:00 AM
Tues, May 17, 2022 @ 2:00 PM

Thurs, Jun 2, 2022 @ 11:00 AM
Tues, Jun 14, 2022 @ 2:00 PM

Quarter 3 Dates

Thurs, July 7, 2022 @ 11:00 AM
Tues, July 19, 2022 @ 2:00 PM

Thurs, Aug 11, 2022 @ 11:00 AM
Tues, Aug 23, 2022 @ 2:00 PM

Thurs, Sept 1, 2022 @ 11:00 AM
Tues, Sept 13, 2022 @ 2:00 PM

Introduction to the Children's Wisconsin IRB

This training session provides practical advice for working with the Children's HRPP Office to help ensure successful IRB submissions and ongoing (regulatory) study management. The goal of this program is to provide research staff – both coordinators and investigators – with important information on the workings of the Children's IRB, while sharing tips and tools for the safe, efficient, ethical, and compliant conduct of research. Register for the next quarterly session!

Office Hours

Join us for Office Hours! Researchers and study staff may sign-up for general questions and guidance that may be provided quickly (generally within 15-minutes or so). Office Hours are held weekly, every Tue 9:30–11:30 AM. Contact Kristin Costello to reserve your slot!

ADMINISTRATIVE UPDATES

NEW AND UPDATED RESOURCES

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

Recently released and updated policies, guidance, and forms:

- GUIDANCE - Reportable Events and New Information 032922
- IRB - REPORTABLE EVENT FORM - 032922
- GUIDANCE - Consent for Continued Participation When a Child Reaches Age 18, 03.10.22

Children's Wisconsin
Human Research Protection Program/Institutional Review Board
Children's Corporate Center
999 North 92nd Street, Suite #120
Milwaukee, WI 53226

Children's Wisconsin
Kids deserve the best.