Human Research Newsletter

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INSIDE THIS ISSUE:

Welcome New IRB Coordinator Olyvia Kuchta!

My name is Olyvia Kuchta and I am joining the IRB office as an IRB Coordinator. I wanted to introduce myself and tell you a little bit about my background.

I am a recent graduate of Ball State University with my masters in Cognitive and Social Psychology. While there, I was an active researcher. I was involved in numerous labs, and worked one on one with several faculty members. I was also involved as a teaching assistant for Research Methods for consecutive semesters. Before Ball State, I graduated with my bachelors in science at the University of Wisconsin-Green Bay. This is truly where I became passionate about research and was involved as well in labs, independent projects, and as a Research Methods teaching assistant. In my free time I like to garden, run, drink coffee, and read. I am hoping to bring my passion for evaluating research to this position and I truly look forward to working with all of you.

Common Rule 2018 (Final Rule) Update

There has been another Notice of Proposed Rulemaking (NPRM) published in the Federal Register that **proposes delaying** the general compliance date of the final rule by another 6 months (until January 21, 2019.) Currently, the compliance date is July 19, 2018 after an initial delay. It may, however, be delayed even further. The full text of the notice can be found here: https://www.federalregister.gov/documents/2018/04/20/2018-08231/federal-policy-for-the-protection-of-human-subjects-proposed-six-month-delay-of-the-general

Did you know... in order to maintain hospital accreditation and compliance with the Joint Commission standards it is crucial that any skill performed on a Children's patient is only performed by Children's Hospital employees or providers who have competencies on file.

Who is considered a Children's Patient? A Children's patient is any person who is being seen for care at Children's hospital regardless if it is for clinical or research care.

What does this mean for my research? The Pediatric Translational Research Unit (TRU) is available to provide these patient care services or can direct you to appropriate personnel.

Corporate Compliance Update: The General Data Protection Regulation (GDRP)

The General Data Protection Regulation (GDRP) establishes protections for the privacy and security of "personal data" about individuals in the European Union (EU). This regulation potentially affects clinical research, as well as other scientific research activities in the United States. The GDRP becomes effective May 25, 2018. The GDRP affects research involving "personal data" about individuals located in EU countries and has extra-territorial reach to the United States. GDRP considers "personal data" to consist of the standard 18 HIPAA identifiers, as well as physical, physiological, cultural, economic, and genetic material.

Although institutions continue to assess the impact of GDRP with regard to research, from what we currently understand, de-identified genetic material and data may be considered "personal data" per the GDRP. It is suggested that researchers obtaining de-identified specimens/data from an EU country (particularly for genetic analysis) obtain consent from the individual as of May 25, 2018. The consent form must be specific regarding the proposed use of the specimen/data, storage/retention for a specific period of time, as well as specific details regarding future use of specimens/data.

Corporate Compliance will continue to provide up-dates regarding GDRP as additional information is acquired.

Effective Date V. Approval Date

We wanted to provide some clarification about effective date versus approval date. The IRB approval stamp provides an effective date and an expiration date.

- The **"effective date"** is the date on which the approved documents and protocol modifications became effective (i.e. the date on which the committee approved as submitted, OR on which all **conditions** for approval were verified as having been satisfied.)
- The **"approval date"** is the date of the board action
    - approving the submission as submitted, **or**
    - approving the submission with conditions to be met before the approval can be finalized

If the board approved the submission **as submitted**, the effective date will be the same as the approval date

If the board approved with submission **pending conditions to be satisfied**, the effective date will be different than the approval date. The approval date will be the date of the board action, the effective date will be the date those conditions are satisfied.

"I received a notification from IRBNet on 1/7/18 that said documents have been published. When I accessed the newly approved consent form it says the effective date is 1/3/18, but I enrolled a subject on 1/5/18 on the previous version because the new consents were not published yet. Am I now non-compliant? What do I do

when I have a subject to enroll in that gap between the board decision and when the documents are published?"

This typically happens with full board review due to the processing time to finalize the minutes and decision letters after a meeting. If a subject is enrolled during this gap, the previous versions of the forms would be used because that is what was available at the time. This would NOT be considered non-compliance even though the effective date on the new consents is 1/3/18. The date on the approval letter would verify the date on which the new consents were available, which may be after the effective date.

When a submission is approved with conditions, the effective date will typically match the date the final approval is published, i.e. the date the conditions were satisfied.

Update – Barcodes on Consent Documents

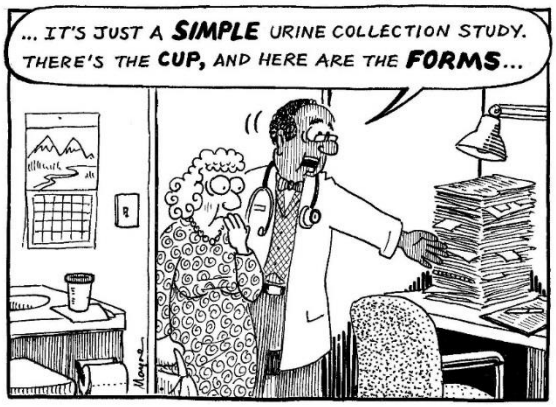
After much further discussion, the IRB will no longer be managing the bar codes on the consent forms. This is a Health Information Management tool for their work process. It is not a regulatory requirement from an IRB standpoint, nor is this an IRB requirement. We will be discussing with HIM to clarify what their expectation is for managing these records from their standpoint and will help to communicate this.

Therefore, going forward (effective May 1, 2018) the IRB will not be checking for the barcode. We will not be asking for this to be added. If it is already on a document that has been submitted, we will not unlock the package specifically to have this removed. We apologize for the back and forth nature of this change.

Submission Checklist

The IRB office has updated our submission checklist. There is a checklist for several different types of submissions, although these are all contained in one document. This is a **guideline** – and lists all **possible** documents that a particular submission might need. Not every document will be applicable for every submission – even those of the same type. There may also be relevant documents not included in the checklist because of the unique nature of a particular study or a reviewers need for specific information on a particular study. It will be up to the investigator to determine if a particular document is applicable to their particular study.

This is available in IRBNet as well as on the HRPP webpages at https://connect.chw.org/departments-services/clinical-departments/childrens-research-institute/human-research-protection/Guidances



Granting Appropriate Access in IRBNet

When creating a project in IRBNet, it is important that the appropriate people are given the appropriate access to the project.

The access levels are:
Read: Users that are granted "Read" access can view project documentation, collaborate with other users and add their signature, but **may not** edit project documents or perform any other administrative functions.
Write: Users that are granted "Write" access can view and edit project documents, collaborate with other users and add their signature, but **may not** grant access to other users, submit packages for review or perform any other administrative functions.
Full: Users that are granted "Full" access can perform all functions without restriction. This includes editing project documents, sharing the project with other users, submitting document packages for review and deleting document packages. Only project owners with day-to-day responsibility for the project should be granted full access. **Users with full access will receive automatic email copies of all project notifications and alerts that are sent to the project owners.**

The person who actually creates the project initially will automatically have full access. They become the "project owner."

The access granted to others on the project should be appropriate to what their role will be.

The IRB expects that the Principal Investigator will have full access to all projects for which they are the PI. Federal regulations require the IRB to "follow written procedures for conducting its initial and continuing review and for reporting its findings and actions to the investigator and the institution." [21CFR56.108 and 45CFR46.103] As the person ultimately responsible for the project, the PI needs to be able to edit and/or manipulate documents and packages as they see appropriate. More importantly, only those with full access will receive the system notifications and alerts from IRBNet. This includes board actions taken, when documents are published, when packages are unlocked for revisions, when studies are due for continuing review or expire, communication regarding suspensions or terminations, etc. There is a regulatory requirement that the IRB

communicate these types of things to the PI. With an electronic system, this is the way that this is communicated and documented. Thus, the PI must have full access granted to receive this information. **This is not negotiable.**

Individuals who are "signing off" on a project as part of the department/ancillary approval process will only need **read access.**

The access granted to other members of the study team is at the discretion of the PI depending on what duties those individuals have been delegated in terms of the IRB submissions. Keep in mind the more individuals that have full access, the more chance there is for manipulation of packages/documents. It is advisable to restrict full access to those individuals who really need it – i.e. are designated as those who are managing the IRB submissions. There may be some on the team who need to able to view the documents, but may not need full access.

Does your study involve Froedtert Hospital resources or subjects? If so, you probably already have or will be asked to contact the Office of Clinical Research and Innovative Care Compliance (OCRICC) at some point to seek Froedtert Health administrative approval. In order for OCRICC to have the ability to grant this approval, their staff needs **read** access to study documents in IRBNet. Previously, research teams had to ask the CHW IRB office to add certain OCRICC staff members individually, sometimes multiple times throughout the life of the project, which was not efficient for anyone involved. We are now changing this process. If you have an existing project involving Froedtert, if you know your new project will involve Froedtert, or if you are amending your existing project to add Froedtert, please 'share' the project with the following individuals from OCRICC: Roberta Navarro, Joanna Delap, Elizabeth Polak, and Leslie Manion and provide 'read' access. (Same way you share projects with pTRU or pharmacy.) This will enable the OCRICC team to review necessary documents as time allows. If you are unsure of whether your project requires OCRICC review, please contact OCRICC to find out (ocricc@froedterthealth.org).

Reminders:

- We have had situations in which a PI creates and manages the submission themselves and is the only person with access to the project. When/if that PI leaves, there is no one else who can get into the package to manage things, to share with a new PI or other team members. There should be at least one other team member, in addition to the PI, who has full access in case there is an absence or departure of a PI.
- When amending packages with the addition or removal of study team members, be sure to update IRBNet access accordingly.
- To be added to a project, a team member must first have a registered account with IRBNet, otherwise they will not show up when trying to share a project.

UPDATES, REMINDERS AND TIPS

- When looking at IRBNet for an update of review progress, seeing "unassigned" does NOT mean that pre-review has not started. This designation has to do with assignment to an IRB and agenda for final review. For full board review, this will populate once the project is assigned to an agenda – review is well underway by the time this happens. If a submission qualifies for expedited review, this will not be assigned to an agenda until an action is recorded, as these are reviewed outside of a convened IRB meeting. When the action reads "pending" this means review is in progress. When the action says "forwarded" pre-review has been completed on the main board and the submission is now pending with the assigned committee. If the action reads "information required" there is likely a document published to board documents ("review details" link) with specific questions that need to be answered, or changes that need to be made within the same package. If the action reads "modifications required" there is likely a document published to board documents ("review details" link) with specific changes that need to be made.

- When information or modifications are requested during the pre-review process, the IRB staff will unlock the package for these to be addressed. However, once the package has been forwarded to a committee, any modifications or information needed is now an official board action. The package will not be unlocked, rather a response/follow-up package will be required to address the request.

- If the IRB staff has unlocked a package during pre-review to either ask the team for specific changes or items, or because the team requested this for a specific update to the package, please do not make any other changes. This can affect the integrity of the information that was already reviewed leading to additional delays.

- When responding to a request for information or modifications needed to satisfy conditions of approval, do not make any changes not explicitly asked for by the IRB. Any other modifications will need to be addressed via a separate amendment package.

- During the review process for all packages, **any** documents that may be used for the study have the potential to be reviewed, **whether they are attached to the package or not.** If the IRB staff notice that a document not included needs to have an update (for example, when the consent has an addition of a blood draw, but the assent was not included and should have this update too) the staff will request that the document is added to the package and updated. Please understand that we are doing our best to help as many study documents as possible be as consistent and compliant as possible. This helps us do our part to ensure subject safety and compliance with federal and state regulations.

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

We're on the Web!

https://connect.chw.org/hrpp

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

Changes that may appear small or administrative on the researcher side may have huge implications on the institutional or regulatory side. We appreciate your patience and understanding with the review process!

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: **Center 4 South, Main Hospital**

Upcoming sessions:

- **Tuesday May 8, 2018 at 2 p.m.** - De-identified Data
- **Thursday May 24, 2018 at 10 a.m.** – De-identified Data
- **Tuesday June 12, 2018 at 2 p.m.** – What does the IRB actually review? Understanding the regulatory criteria for approval.
- **Thursday June 28, 2018 at 10 a.m. –** What does the IRB actually review? Understanding the regulatory criteria for approval
- **Tuesday July 10, 2018 at 2 p.m. –** TBD
- **Thursday July 26, 2018 at 10 a.**m. - TBD

CRI Quarterly Education Session – May 22, 2018

The topic for this session is Research Study Budget Development and Negotiation

Please forward your questions or concerns to Jeff Crawford at JCrawford@chw.org in preparation for the session on May 22nd.

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

IRBNet Document Library and Website Updates

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

Forms posted:

- Revised - Continuing Review form
- New - Submission Checklists
- New - Submission Guidance – Continuing Review