Human Research Newsletter

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The Revised Common Rule

No More Delays

In their January newsletter the Office of Human Research Protections (OHRP) confirmed that there will not be any more delays in the implementation of the revised Common Rule. This will take effect on January 21, 2019

We have tried to anticipate and plan for the transition and new requirements with very limited guidance from the federal agencies. We are told guidance will be forthcoming. As such, we may need to "course correct " as we go and there may be bumps along the way. Thank you for being patient and understanding as we implement these changes.

Summary of Revisions to the Common Rule (rCR)

Federal Regulations at 45 CFR 46, otherwise known as "the Common Rule", are the set of Federal Department of Health and Human Service regulations in effect to protect human research subjects.

On January 21, 2019 revisions to these regulations will take effect. These regulatory changes apply to all Federally-funded research. Additionally, there may be studies for which these regulations must be applied due to terms of a contract or grant.

IRB oversight for federally-funded collaborative research projects located in the U.S. will be required to use a single IRB starting **January 20, 2020**. The NIH currently requires the use of a single IRB. This requirement will be expanded to

all federally funded research by January 20, 2020. There is still one year before this is a mandatory requirement, and there will be additional information forthcoming closer to this implementation date.

Investigators and study teams need to understand these changes and to which of their research projects they apply. The primary changes that will directly affect investigators and study teams are as follows:

- Informed Consent requirement changes
- Continuing Review regulatory changes
- Exemption categories

The full text of the revisions to the Common Rule published in the Federal Register can be found here

The regulatory text of 45 CFR 46 can be found here

Informed Consent:

1. **"Key information"** must be presented at the beginning of the consent form. This includes a concise summary of study activities, risks, and benefits presented to research participants at the start of the consent. This new section is intended to help a subject decide why they would or would not want to participate in the research protocol. The new templates provide a guide for what information to incorporate in this section.

   Please keep in mind the intent is not to "cut and paste" all the details from sections of the consent and just duplicate this information at the front of the consent. The template is designed to limit the amount of information that can be included in this section. This will require some thought about what would be considered key information and it should be presented concisely. This section is a summary, with all the details later in the document.

   There will be a learning curve, for investigators as well as IRB reviewers, getting comfortable with how to approach this new section. The Office of Human Research Protection (OHRP) plans to provide guidance on this, but as of this writing it is not yet available. The CHW IRB office will provide resources, samples and guidance as they become available.

2. **Elements of consent:** There are **new** required elements for the consent document. The **new templates** incorporate these elements and the CHW IRB office will need to make sure these are included.

Lingo: These changes to the regulations are being referred to in a number of different ways, depending on the source, and used interchangeably. Some things you may see that refer to the Common Rule as of 1/21/19 include:

- 2018 Common Rule (as opposed to pre-2018 Common Rule)
- The Final Rule
- The Revised Common Rule
- The Final Rule to Revise the Common Rule

For more details see OHRPs page of Terms Related to the Revised Common Rule

When you protocol involves	Must be included in the consent
Collecting identifiable private information or identifiable biospecimens	A statement indicating whether: (must choose one or the other) • Identifiers might be removed and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator **OR** • The subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.
Collecting and using biospecimens	A statement indicating whether: • Biospecimens may be used for commercial profit, and whether the subject will share in that profit • The research will or might include whole genome sequencing (sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen)
Research that could produce clinically relevant individual results	A statement indicating whether the clinical results, including individual research results, will be returned to the subject, and if so, under what conditions.

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.

3. **Posting requirement:** For federally-sponsored clinical trials, a copy of an approved consent form must be posted to a "publicly available, federal website" after the last subject is recruited but no later than 60 days after the last study visit by any subject. ClinicalTrials.gov is an acceptable website. Investigators are responsible for posting their consents within this time frame. Additional guidance is still forthcoming from OHRP, and more information about this requirement will be provided as we receive additional regulatory guidance.

Please note: *the new regulations contain a very specific provision for a method of limited IRB review and approval of "Broad Consent" for unspecified future use of identifiable data/specimens. CHW will* ***not*** *implement this new regulatory option at this time. This provision in the regulation is* ***optional****. Most large academic institutions are not implementing this provision because of the complex provision for institutional recording keeping track of those who "opt out". Please note this does not interfere with the ability to have IRB reviewed protocols/consents that contain broad provisions for collecting, sharing and using biological samples and data.*

Continuing Review

Continuing review is no longer required for:

1. minimal risk research that meets the regulatory criteria for expedited review categories
2. studies where the only remaining activity is data analysis of identifiable data/bio specimens or activities to obtain only follow-up clinical data

Please note: this does not eliminate the need to keep the IRB office updated on these studies. While the IRB is not required to conduct continuing review of these studies, the HRPP will still require an annual status report to keep the research active. We are refining the details of the process and forms, and will release information as it is available. Keep in mind this provision does not become relevant until new studies submitted after January 21, 2019 are up for continuing review which will be a year from now.

Also note: this does not apply to FDA regulated research. Any project that falls under FDA regulations will continue to require annual continuing reviews.

Exemption Categories

The categories for exemption have expanded. There are now 8 categories of exempt research. The regulations provide a list of "exempt" research activities that meet the definition of human subject research, but may be conducted without applying all of the IRB review requirements.

Some of the criteria for category 2 have limitations on applying these to research with children and only apply when adults are subjects. There is also a new exemption category, category 3, for benign behavioral interventions. However, this only applies when adults are research subjects.

Category 7 and 8 are new categories, however, these depend on the use of broad consent which CHW will not be implementing, so these exemption categories will not apply to research at CHW.

Overall, the biggest change that will affect CHW in terms of exemption categories is regarding research involving the secondary use of specimens and data acquired for purposes other than research. The new exemption criteria are expanded to include the use of data and documents that will be collected in the future (not just those that already exist) and in some cases, even when identifiers are maintained. This expansion will reduce the number of protocols that need to undergo expedited review and instead may now be considered exempt. Investigators are still required to complete a form to request an exempt determination by the IRB administrative office. There will be additional communication when this form is published and education regarding these submissions will be available and announced when available.

To what does this regulation (the Common Rule) apply?

Unless a study meets the criteria for one of the exemption categories, "this policy applies to all research involving human subjects conducted, supported, or otherwise subject to regulation by any Federal department or agency that takes appropriate administrative action to make the policy applicable to such research." (45 CFR 46.101)

This means that there is no requirement to apply the Common Rule unless a study is federally funded, or is this is required by the terms of a grant, contract or other agreement.

REMINDER: Studies regulated solely by the FDA remain unchanged in terms of regulatory compliance.

There is a summary chart of the exemption categories, used with permission from the University of Kentucky Office of Research Integrity, available on IRBNet and on the HRPP web site.

CHW's Transition Plan for Implementing the Revisions to the Common Rule

We will be publishing an addendum to the CHW HRRP/IRB policies and procedures which describe the variations in requirements and procedures that the CHW HRPP/IRB and investigators will adhere to for research subject to the revised Common Rule that is IRB approved or determined exempt on or after January 21, 2019.

While this SOP addendum is in effect, any study that is solely FDA-regulated or does not require compliance with the revised Common Rule by terms of a grant, contract or other agreement, will be reviewed in accordance with pre-2018 Common Rule requirements, until such time as a decision is made and documented to transition to the revised Common Rule provisions.

So, what does this mean for investigators?

Studies that are currently approved and open: business as usual

At this time we do not anticipate there will be any changes to studies that are currently open. Your study will continue to be reviewed and approved according to the policies and regulations in effect today (i.e. under the pre-2018 Common Rule; FDA regulations which are no changing; and current policies at CHW). In the future we may decide on a protocol by protocol basis to transition a study to the revised Common Rule. We will provide additional details if and when that decision is made.

Studies submitted and/or approved on or after January 21, 2019

Currently and until further notice, we will only review studies under the revised Common Rule provisions if your study is federally funded, or if this is required by terms of a grant, contract or other agreement.

For all other studies, it will be business as usual and studies will be reviewed under current policies and pre-2018 requirements (the "old" Common Rule).

Studies that are awaiting approval on January 21, 2019

If you have a protocol that is under review, but not yet approved, on January 21, 2019 it is possible you will receive requests for additional changes in order to bring the protocol/consent into compliance.

We have been and will continue to screen all new submissions. Investigators will be contacted directly and provided with specific instruction if it appears the revised Common Rule applies to the study.

What is the CHW IRB Working On to Prepare? (Hint: LOTS)

The CHW IRB office would like to apologize if we have not been as responsive to investigators and study teams lately. These revised regulations require a great deal of updating to forms/policies/processes. In addition to what the investigators will notice as a direct impact, "behind the scenes" there is a great deal more.

Informed Consent Template Revisions:

There will be new consent templates posted in IRBNet. We anticipate these will be posted the week of January 21, 2019. There will be email communication when these are available for use. These templates replace the current CHW consent templates and once they are available should be used for **ALL** new studies. These new template incorporate the requirements of the common rule, and are consistent in format with the templates used by the MCW IRB.

IRB Checklists/Forms/Processes/Investigator Tools

Most of our processes and documents used by reviewers and analysts require updating. In addition, we will revise the submission checklist. There will also be an update in the coming weeks to the funding section of the registration page asking specifically if a non-government funding source requires compliance with the common rule. Investigators have access to this information through their grants/contracts with their funders.

Note: FDA has indicated the consent revisions of the Common Rule are permissible for FDA regulated research. See FDA guidance regarding this.

Policies

As mentioned above, we have created a policy addendum to incorporate the regulatory revisions while we update individual policies. As a next step we will continue to update all affected individual policies and informing the research community when these are published.

New Study Applications

We have been working on a complete revamp of our new project application form and are now working to incorporate the revised Common Rule provisions before releasing this. We are also working on a new exempt study application form. There will be communication to alert the research community when these are available for use as well as targeted education opportunities.

Annual Status Updates

As stated previously, while the revisions to the Common Rule change the requirement for annual continuing review for certain studies, there will still be a process by which investigators will provide the IRB with annual status updates for these studies. We are refining the details of this process and forms, and will release information as it is available.

Education

We will be scheduling education sessions regarding specific aspects of the revisions to the Common Rule, as well as the new forms and tools as they become available. Upcoming monthly small group education sessions will cover Common Rule topics, and there will be additional educational opportunities announced in the coming months.

Additional information about the regulatory changes and transition provisions will be provided as we receive additional guidance from the regulatory agencies, and as we fine tune our materials and processes. Please feel free to contact the IRB office with questions at any time.

A Message from CHW Corporate Compliance

CHW Epic access for research staff (CHW non-employees) will expire if CHW Epic is not accessed within 60 days. CHW IS does send out emails at the 45 day mark to inquire as to whether or not the CHW Epic access continues to be needed. This email is sent to the individual who requested access for the research staff and is required for security reasons.

Epic access is also dependent upon re-setting your password and CHW IS sends out emails indicating that your password will expire.

If CHW IS does not receive a response to the 60 day notice, or the individual does not re-set their password as required by CHW Security policies, the individual's account will be deleted.

Please be aware of your obligation to maintain your access to Epic.

PEDIATRIC TRU UPDATES

EPIC Upgrade Reminder: Jeff Crawford is your Research Epic Credential Trainer. If you ever have any research related questions, comments, or concerns please contact Jeff – jcrawford@chw.org or 414-266-7254

Please join the Pediatric TRU Staff for an informal networking session for research support staff

Who: Research Coordinators, Research Assistants, and Research Nurses
Why: Meet our newest Nurse – **Carisa Pincolic** (if you haven't had a chance to say hello yet) & get to know other people in like roles in the pediatric community
Where: Center 4 South – Pediatric TRU Conference Room
When: Thursday, January 31 – 2-3pm

Light snacks provided by the TRU

Please RSVP if you plan to attend so I know how much food to prep for our session. Also, please forward to anyone who I may have inadvertently missed on the invite.

Epic Research Billing Reminder
If research charges will be added to a patient's hospital encounter within Epic, please be sure to send a Charge Notification Form to Barb Hodges or Mary Gruenwald within 24 hours of the encounter (inpatient or outpatient). Barb and Mary will transfer the research related charges to the study account as indicated on the form to ensure that patient families are not charged for research related study procedures.

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.

For more information and updates on education opportunities visit the HRPP webpages

Children's Hospital of Wisconsin Human Research Protection Program/Institutional Review Board

Children's Corporate Center
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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, CIP, CCRP at MMartin@chw.org

These will meet in the TRU: **Center 4 South, Main Hospital**

January 24th, 2019 @ 10:00am, Revised Common Rule

February 5th, 2019 @ 2:00pm, Revised Common Rule

February 21st, 2019 @ 10:00am, Epic Research Billing

March 5th, 2019 @ 2:00pm, Epic Research Billing

March 21st, 2019 @ 10:00am, TOPIC TBD

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/guidance recently posted:

- New Informed Consent/Assent form templates
- Guidance: Exemption Categories Tool
- Policy and Procedure Addendum: Implementing the Revised Common Rule (will be posted in the very near future)