Ascension

Ascension Wisconsin

Research Integrity and Protection Newsletter

January 2019

Revised Common Rule is Effective January 21, 2019

On January 19, 2017, the Department of Health and Human Services and fifteen other federal agencies issued revisions to the regulations governing human subjects research (called the Common Rule).

The changes to the Common Rule DO NOT APPLY to research that is regulated by the FDA, but for all other research the changes become effective for all **NEW research** reviewed by the IRB on or after January 21, 2019. All **ongoing research** approved before that date will remain under the Current Common rule (pre- 2018 requirements), until such time the study closes or is transitioned to the new rule.

The IRB Guidance outlining key changes that will impact researchers and the transition plan for ongoing studies is included below.

IRB SOP & GUIDANCE UPDATES

The following IRB SOPs and Guidance documents have been recently updated. All IRB SOPs and Guidance Documents are available in Mentor

IRB Guidance: Revised Common Rule Key Changes and Transition Plan

Summary: Key changes of the Common Rule and transition of studies from the pre-2018 to the new Revised Rule.

- Key changes and the impacts on researchers
- Criteria and process for transition to the New Revised Rule

IRB- SOP-302: Human Subject Research Exempt from IRB Review

Summary: Revised to address new categories and requirements of the Revised Common Rule and align with other processes including:

- Applicable after 1/21/2019
- Reference of new categories for exemption
- Notification of study completion or closure (applicable only for studies initially approved on or after 1/1/2019)

IRB Guidance: Exempt Review

Summary: To provide guidance on new categories of the Revised Common Rule and requirements for Exempt research.

- Outlines submission process, new categories and applicability
- Exempt categories are broadened under the new common rule and more studies will likely qualify for Exempt Review

Other SOPs with Minor updates

Summary: Updates to reflect common rule changes and other minor clarifications and corrections.

- Meeting Conduct
- Flexibility
- Lapse (Expiration) of IRB Approval
- Meeting Minutes
- Expedited Review

UPCOMING RESEARCH EDUCATION EVENTS

Updates and Changes to the SOPs, Mentor and the Common Rule.

The IRB will host a Q&A session via Skype

Thur. 1/17 9:30-10am:
Join Skype Meeting
1 (888) 444-5443
Conference ID: 27650281

Or contact IRB staff during IRB office hours

Are you Smarter than Research Integrity & Protection Staff?

Teams of researchers compete to see if they are smarter than RI&P staff in this "Are You Smarter Than a 5th Grader" style education session.

Tue. 2/12 3:30-4:30pm
Main Office in Glendale Service of the Poor Room (3WC30)
Or Join Skype Meeting
1 (888) 444-5443
Conference ID: 36608877

MENTOR UPDATES

The revised Mentor User Manual will be available in Mentor on the main IRB page.

NEW: Eliminating Paper Forms and Implementing Electronic PI Signature for Amendment Submissions

Summary: This change was initiated after input from researchers, staff, and the IRB. The goal is to reduce administrative work and decrease the time to receive IRB approval.

This change was implemented in October for Reportable events and will be effective for Amendments beginning 1/21/2019.

Changes Include:

- Elimination of paper report forms
  - Questions will be entered directly in Mentor
  - You can start and come back to the questions
  - Print the answers submitted to a pdf for the study file

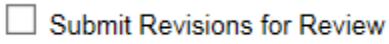
- Electronic collection of the PI signature via Mentor
  - PI's will get an email to sign a submission
  - Click to review and sign the submission, NO log in required
  - The PI must sign before the report is submitted to the IRB

NEW: Mentor Function for Submitting IRB Requested Revisions

Summary: Updated Process for submitting requested revisions prior to the IRB review to align with the process of revisions requested after IRB review and allow study staff to work on the submission in Mentor prior to submitting it to the IRB.

Overview of change:

- Beginning with Revisions requested on or after 1/21/2019
- If there are revisions requested prior to the IRB review, you will receive a standard Mentor notification outlining the revisions. This will replace the Mentor message or email currently used.
- You will also need to submit the changes to the IRB. Once you have all items updated/uploaded in Mentor, check the box to submit the revisions to the IRB. This replaces and Mentor message or email that you currently send; staff are automatically notified when the box is checked.
- You will also see a checkbox near the top left of the submission.



UPDATED: Main Protocol Page Questions

Summary: The format of some questions related to funding, Sponsors and regulatory oversight listed on the main study information for new protocols will be updating.

Overview of change:

- The content of the questions is the same, only the format and order are changing.
- This effects new Protocols after 1/21/2019.

Revised Common Rule Key Changes and Transition Plan

On January 19, 2017, the Department of Health and Human Services and fifteen other federal agencies issued revisions to the regulations governing human subjects research (called the Common Rule). Most of these changes go into effect on January 21, 2019.

The key changes that will impact researchers and the implementation and transition plan are outlined below.

A copy of the new Revised Common Rule and related information is available on the OHRP website.

Applicability of the Common Rule

The changes to the Common Rule DO NOT APPLY to research that is regulated by the FDA, Dept. of Justice (DOJ) or Consumer Product Safety Commission (CPSC).
For research regulated by another federal agency and all other research the Revised Common Rule becomes effective for all new research reviewed by the IRB on or after January 21, 2019.
All ongoing research approved before that date will remain under the Current Common rule (pre- 2018 requirements), until such time the study closes or is transitioned to the new rule. See the Transition section below for more details).

Key Changes

Exempt Research

The Revised Common Rule broadens the types of research that qualify for exemption. Several exempt categories have been revised, and there are new categories of exemptions. The Exempt Review Guidance shows how the categories have changed. Note that some exemption categories require limited IRB review, which is a new type of review.

Impact of Changes:

- Research Approved before 1/21/2019: No change after 1/21/2019
- Research Approved on or After 1/21/2019: Follows new Common Rule categories, some of which require limited IRB review
- New IRB process/SOP requires notification of closure to the IRB

Continuing Review

The Revised Common Rule removes the requirement for continuing review for research that is minimal risk research OR greater than minimal risk research ("Full Board") research that is in long-term follow-up or data analysis only.

Impact of Changes:

- Research Approved before 1/21/2019:
  - When the IRB conducts continuing review for ongoing research, the IRB will determine whether transition to the Revised Common Rule would be allowed and whether it would be potentially advantageous to the research.
  - This will be considered only on non-regulated research (not federally funded, not FDA regulated).
- Research Approved on or After 1/21/2019:
  - New minimal risk research will not automatically undergo continuing review by the IRB (unless it is FDA-regulated).
  - The IRB may require continuing review for special circumstances such as studies involving conflict of interest, IRB reliance or prior compliance concerns.
  - Even when continuing review is not required, investigators remain responsible for updating the IRB about adverse events and other unanticipated problems, seeking IRB approval for changes to personnel, protocol amendments, recruitment materials, etc., and informing the IRB when the research is complete.

Informed Consent

Additional elements of informed consent are required to be included in consent forms. The IRB Required Elements of Consent Guidance shows Common Rule revisions.

Consent forms will now require a concise summary of "key information" that is most likely to assist a prospective subject in understanding the reasons why one might or might not want to join the research.
This summary must include:

- Study activities, risks and benefits presented to research participants in the first few pages of the consent document.
- This section must be organized in a way that facilitates understanding.
- Consent forms of previously approved studies will not need to be updated to meet this requirement, unless federally funded and open to enrollment.

Impact of Changes:

The Ascension WI IRB consent templates have already been updated to include these changes format.

The new Common Rule requires certain clinical trial consent forms be posted on a government website. This requirement applies to studies that are conducted or supported by a federal agency and is usually done by the study Sponsor. The posting must occur no more than 60 days after the last study visit by any subject.

Single IRB Review

IRB oversight for most federally-funded collaborative research projects located in the U.S. will be required to use a single IRB (commercial, academic, or hospital-based) starting January 20, 2020. Additional information will be provided later.

Transition from the pre-2018 Common Rule to the Revised Common Rule

The Ascension Wisconsin IRB Office's transition plan is based on one of the possible transition plans and timelines that OHRP has developed and posted on their website.
Currently approved studies (approved before 1/21/2019) will have the opportunity to transition to the Revised Common Rule requirements if they meet the following criteria:

- Are "non-regulated research" (not federally funded, not FDA regulated)
- One or more of the following are true:
    - Have previously been granted a waiver of informed consent
    - Are closed to enrollment with subjects in long term follow up (only collection of clinical care data)
    - Remains open for data analysis only

At the time of the next continuing review, IRB staff will work with the PI and study team to verify the requirements are met and document the transition. This process may also be done at other times on a limited case-by- case basis.