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Special Edition Newsletter
Aurora Research Subject Protection Program (RSPP)
Institutional Review Board (IRB)

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The Aurora RSPP Office will be publishing several Special Editions of our newsletter to discuss the regulatory changes included in the revised Federal Policy for the Protection of Human Subjects (aka the HHS "2018 Common Rule") and the processes for implementation for studies under the purview of the Aurora IRB. **The changes included in the revised Rule are scheduled to go into effect on January 21, 2019.** All new studies initially approved on or after January 21, 2019 that are HHS-regulated or unregulated will be reviewed using the 2018 Common Rule regulations [from this point forward "2018 Rule"].

Stay tuned for information on changes required by the 2018 Rule for informed consent and new/revised exempt research categories.

Note that the 2018 Rule changes do not impact research studies approved by the Aurora IRB PRIOR to the implementation date of January 21, 2019 – UNLESS the study is transitioned to the 2018 Rule regulations by the Aurora RSPP. You will be notified by the Aurora RSPP office if transitioning occurs.

The following graphic depicts the important changes in the 2018 Rule. This Special Edition newsletter discusses **changes to the Continuing Review requirements** and **transitioning of currently approved research to the 2018 Rule**.

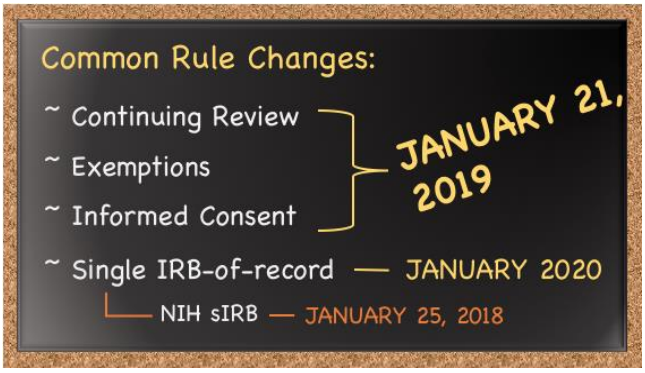

Image reprinted from University of Michigan Research Ethics & Compliance website

2018 Rule changes relative to Continuing Review requirements

As a burden reducing effort, the 2018 Rule removes the requirement to conduct continuing review of ongoing research for studies that undergo expedited review and for studies that have completed study interventions and are merely analyzing study data or involve only observation follow up in conjunction with standard clinical care. *~2018 Rule: Federal Register Volume 82, Number 12 (Thursday, January 19, 2017)*'

What does this mean?

Effective January 21, 2019, newly submitted/approved research that falls under the regulations of the Common Rule (i.e. federally funded and unregulated research nonexempt human subject research) **Continuing Review <u>may</u> not be required** for the following types of research:

<u>Most</u>***** studies that are:

- Initially reviewed under the expedited review process
    - Studies qualifying for expedited review must be of no more than minimal risk and meet one of the OHRP Expedited Review Categories
- Greater than minimal risk research where subject intervention/interaction is complete and in which activity is limited to either final analysis of identifiable data/biospecimens or involve accessing follow-up clinical data from procedures that subjects undergo as part of their standard of care

*****Although most research included in these categories will qualify, per the 2018 Rule, it is left to the discretion of the IRB to determine whether continuing review is necessary. Such a decision will be documented and provided to the PI.

Some reasons for maintaining the continuing review requirement include:

- The project is regulated by the Food & Drug Administration (FDA) or by another sponsor that requires continuing review
- The project involves additional regulatory oversight, such as an Investigator's Conflict of Interest
- A protocol amendment or significant new finding reveals information that requires additional oversight. The IRB will evaluate the decision for ongoing continuing review at the time of submission of this new information
- The investigator has had previous serious non-compliance or a pattern of non-serious non-compliance

Researchers will be informed of the need for continuing review in their approval letter.

This change in continuing review requirements DOES NOT APPLY to research studies that are regulated by the US Food & Drug Administration (FDA).

Transitioning <u>currently-approved</u> research to 2018 Rule

HHS has determined that currently-approved research may be transitioned to the 2018 Rule to take advantage of its burden reducing provisions. The Aurora RSPP has created a process that will be used to determine if a currently-approved research study qualifies for transitioning to the 2018 Rule.

Aurora RSPP Process for transitioning a currently approved study to the 2018 Rule

In order for currently approved research to take advantage of the burden reducing provision of "no continuing review (CR) necessary" included in the 2018 Rule, the Aurora RSPP office will consider the transitioning of each research study at the study's next scheduled continuing review beginning in January 2019.

The Aurora RSPP will first determine the regulatory status of the research (i.e. HHS regulated, unregulated, FDA regulated).

- If FDA-regulated research, the study **cannot** be transitioned.
- If HHS-regulated or unregulated research, the study **will be** transitioned to the 2018 Rule as long as:
  1) the study meets the criteria for 'no CR' status:
     - No greater than minimal risk research (meets an expedited category)
       OR
     - Greater than minimal risk research in which there are no remaining subject interventions/interactions, and the remaining research activities are limited to collection of clinical standard of care data or the analysis of identifiable data/biospecimens
  2) the Aurora IRB determines that there are no conditions that warrant continued IRB oversight via the Continuing Review process (see * above)

In order for a research study to be transitioned, the study must meet ALL of the regulations in the 2018 Rule. This means that, if the study is HHS-regulated and still enrolling research subjects using a research informed consent, the consent document MUST be revised to the 2018 Rule requirements BEFORE transitioning will occur. Unregulated research that is still enrolling subjects using a research informed consent does not need to include the 2018 Rule requirements for the informed consent document per Aurora policy 811.

Before continuing review occurs, the Aurora RSPP Office will work to identify those studies 'no CR' qualifying studies that remain open to subject enrollment and use a research informed consent document. The RSPP will inform the research team of the need to update the informed consent document in order to take advantage of transitioning and the burden reducing provision of 'no CR'. The study cannot be transitioned until the research informed consent document has been updated/approved.

ONLY the Aurora RSPP/IRB may make the decision to transition a research study to the 2018 Rule. The PI/research team is NOT able to make the transitioning determination. Continuing Review is required for all non-exempt human subject research until the Aurora RSPP informs the study team otherwise.

By mid-2022, all HHS-regulated and unregulated human subject research – whether it meets 'no CR' status or not – will be transitioned to the 2018 Rule. This will allow the Aurora RSPP to function under one set of Common Rule regulations.

The Aurora RSPP will work with research teams at their 2021 continuing review to identify what is required of them to transition their study to the 2018 Rule. This may include revisions to consent document(s) and posting of the informed consent document on public website. More information on the 2018 Rule regulations as it pertains to the informed consent will be provided in a later newsletter.

In summary:

If the currently-approved research study can be transitioned to the 2018 Rule:

- The submitted continuing review will be approved, and the PI provided written documentation on the decision to transition the study to the 2018 Rule, including a decision on the continuing review status
- If no further continuing review is required, an annual Reporting Obligations notice will be sent to the PI until the research is closed with Aurora IRB

If the research study cannot be transitioned to the 2018 Rule:

- The submitted continuing review will be approved and will continue to be requested by Aurora RSPP
- The Aurora RSPP will evaluate the study at the next scheduled continuing review to see if it meets transitioning criteria

IMPORTANT THINGS TO NOTE ….

- Even when continuing review is not required for a project, the research team is still OBLIGATED to submit the following:
    - Changes in the research (using an Aurora RSPP Change form)
    - UPIRSO's (using an Aurora RSPP Unanticipated Problem Reporting form)
    - Significant new information (using an Aurora RSPP Significant New Findings form) that does not rise to the level of a UPIRSO but may affect a subject's willingness to remain in the research
    - Noncompliance (using a Noncompliance Reporting form)
- Submit an Aurora RSPP Final Report form once your research study is completed, and/or personal identifiers are removed from the data/biospecimens, and all codes and keys are destroyed so that your study can be closed with the Aurora IRB.
- You will be reminded of the above obligations via an Annual Notice.
- If/when the FDA harmonizes with the 2018 Rule, more information will be provided by the Aurora RSPP on the transition of FDA-regulated studies.

Aurora IRB Review Fees

As of **November 1, 2018**, IRB Review Fees are being charged by the Aurora RSPP for any research conducted at Aurora Health Care (see **IRB Review Fees** guidance on the Aurora RSPP website) unless your study qualifies for a fee waiver.

Transition to the 2018 Rule and a "No CR" status does NOT eliminate the requirement for IRB review fees. Unless your research study qualifies for an IRB review fee waiver, you will be invoiced for annual IRB review fees each year that your study remains open. Waiver criteria are noted in the IRB Review Fees guidance on the Aurora RSPP website, and are included on all new submission applications. Contact the Aurora RSPP Office (414-219-7744) with questions.