Subject: Common Rule Change Implementation Plan-Updates

Researchers and Research Staff,

The federal rules governing human research, called the Common Rule, was originally adopted in 1991 by the U.S. Department of Health and Human Services and 15 other Federal Departments and Agencies. Following a one-year delay, the revised Common Rule will go into effect on January 21, 2019.

The following is a brief highlight of those changes that will directly affect you as part of the research community. Investigators should fully read this email to remain compliant with the Revised Common Rule. Faculty advisors for current or upcoming student research with human subjects are asked to share this information with the student researcher.

Updated policies, investigator guidelines, and templates will be posted in the Huron IRB software Library and Help Center on the IRB website
http://www.research.ucf.edu/Compliance/IRB/Investigators/forms.html

The IRB will provide a workshops on the new Common Rule during scheduled IRB at Your Doorstep Events. You can contact the IRB office to schedule a workshop.

Continuing Review

- The Revised Common Rule removes the requirement for continuing review for minimal risk research (i.e., research approved as Expedited) unless the research is FDA-regulated (ie: involves and IND, IDE, or HUD). If the study is FDA-regulated, then there is no change, and yearly continuing review is required.
- When the new rules go into effect, new research approved as Expedited will not automatically require continuing review by the IRB unless it is FDA-regulated. The IRB may require continuing review for special circumstances such as studies involving a conflict of interest, IRB reliance, or prior compliance concerns.
- In order for the University to keep track of active minimal risk studies, as of January 21, 2019, protocols approved as Expedited without required continuing review will include an annual "Status Report" to determine if the study is still active or if a study closure is needed. Researchers will receive notification from the IRB when the status report is due and are required to submit the annual report as part of the study coverage continuation.

Important Note: 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. Researchers are responsible for completing study closure requests when all human subjects research activities related to a study are complete.

Informed Consent

There are a few changes to the informed consent rules and these changes have been incorporated into the new HRP-502 and HRP-502b Informed Consent templates with the version date 11/19/2018.

The following two changes affect investigators and study teams directly:

- The standard consent template has been changed to 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.
- There is also a statement required to be added to the data confidentiality of the consent to inform subjects of the potential use of their de-identified data.

Changes to Exempt Categories

The Revised Common Rule broadens the types of research that qualify for exempt study determination. A revised HRP-255 Request for Exempt Determination form that includes the updated categories will be available in the Huron IRB document library and on the IRB website starting January 15, 2019. Exempt determination requests submitted after January 15, 2019 11:59 pm EST must use the revised HRP-255 with the form version date 1/21/2019.

January 21, 2019, is both the effective date and the compliance date for the new Common Rule. Therefore, the changes require us not to finalize exempt determination requests between January 16, 2019, and January 21, 2019. Any such submission received between this timeframe will be sent back to the PI to resubmit under the new rules.

Additional guidance documents regarding the specific changes to Exempt Categories will be available in the Huron IRB software “Help Center”

Single IRB Review

You are probably aware that as of January 25, 2018, all multi-center **NIH-funded** studies require the investigators to use a single IRB review for the local sites.

Starting in January 2020, single IRB review for studies conducted or supported by other federal agencies will be required as well. Note that the funding agency usually determines which IRB will serve as the sIRB. The UCF IRB will not necessarily serve as the sIRB for your funded study and may only serve as the sIRB for unfunded studies in specific cases.

Impact of the Changes on Research approved before and after January 21, 2019:

1. All new protocols approved after January 21, 2019, will be approved under the new Common Rule, regardless of study risk, funding, or funding source.
2. Other than as stated above regarding revised informed consent forms there will be no other changes to the Full Board protocols as it relates to the new Common Rule.

3. All Expedited protocols regardless of funding or funding source approved before January 21, 2019, will still be required to provide a "Continuing Review" based on its expiration date. If the researcher wishes to transition the study to the new Common Rule, use of the 11/19/2018 HRP-503 Protocol and HRP-502 or 502b is required at time of first continuing review or modification request in the Huron IRB software. Unless under FDA oversight or as otherwise determined by the IRB, subsequent continuing reviews will be replaced with a "Status Report".
4. Studies issued an Exempt or Not Human Subjects Research determination letter prior to January 21, 2019 do not need to take any actions unless changes are made to the study. Request a new Exempt or Not Human Subjects Research determination by using the most recent request form version posted in the Huron IRB Library.

Huron IRB Software System

Minor changes will be made to the software to accommodate study review using both the Pre-2018 and new Common Rule requirements. These changes are mostly related to the IRB office procedures and are expected to have minimal impacts to the research community.

In addition to Common Rule change guidance documents, the IRB will post a revised HRP-103 PI Manual in the Huron IRB library. In response to comments from the research community, the IRB is also developing a protocol template specific to Social Behavioral Educational studies. These documents will be released January 22, 2019.

Please contact the IRB office at irb@ucf.edu or 407-823-2901 with any questions or concerns.