HSC Announcement: Revised Common Rule (45 CFRF 46, Subpart A)

Implementation of the final revisions to the Federal Policy for the Protection of Human Subjects (a.k.a. the "Common Rule") will go into effect on ***January 21, 2019***.

Summary of major changes that affect the research community:

- Changes to the informed consent process, including documents and documentation
- Continuing review for *certain* minimal risk research may no longer be required
- Various clarifications and addition of new categories of exempt research
- Single IRB of Record (sIRB) requirements (effective January 25, 2020 – *for NIH studies, effective date was January 25, 2018*).

iRIS will go offline in January prior to implementation of the Revised Common Rule

The University's Human Research Participant Protection (HRPP) offices will close iRIS for a few days to implement and test the regulatory changes in the system. Below is the planned timeline:

December 20, 2018	iRIS will be closed to new study submissions on Dec. 20th at **5:00 p.m.** Continuing reviews, Modifications, Determination Worksheets, and other submissions will continue to be accepted.
Dec. 21, 2018 – Jan. 15, 2019	Time needed for IRB to review new studies submitted prior to December 20, 2018, get responses for stipulations, and grant final IRB approval.
January 15-16, 2019	Education Town Halls for OUHSC research community (including videoconference to the Tulsa campus)
January 16, 2019	iRIS down for upgrade and testing.
January 22, 2019	iRIS up to accept all submissions.
January 2019	Update and publish guidance on HRPP website; post new consent template(s), policies and procedures, and transition details.

NOTE: The above schedule should allow enough time for the HRPP / IRB to complete its review of submissions prior to January 21st to remain under the "pre-2018 Rule." Research approved January 21, 2019 and beyond *must* meet the updated requirements of the "2018 Rule", and is subject to the updated consent and exemption requirements. **Exceptions to the above schedule or urgent submissions will be considered for acceptance on a case-by-case basis. Please contact the HRPP Office at 405-271-2045 prior to submitting any new studies in iRIS during the new study "freeze" window.**

More information will be provided on the HRPP/IRB website as it becomes available. Feel free to contact the HRPP Office at 405-271-2045 if you have any questions or concerns. Thank you.