2018 Common Rule Revision
Code of Federal Regulations – Human Subjects Research
Part 46 Summary – Effective 1.21.19

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). These changes went into effect on January 21, 2019.

The federal Office of Human Research Protections (OHRP) describes the purpose of the regulatory changes:

> *The new rule **strengthens protections** for people who volunteer to participate in research, while ensuring that the oversight system does not add **inappropriate administrative burdens**, particularly to low-risk research. It also allows **more flexibility** in keeping with today's dynamic research environment.*

OHRP posts a copy of the new rule and related information at: https://www.hhs.gov/ohrp/regulations-and-policy/regulations/finalized-revisions-common-rule/index.html

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. These changes to exemption will apply to research that is federally funded or supported. Below are additional guidance documents on select topics which will affect exempt research:

- Guidance on Exempt research 01/2019
- Guidance on Benign Interventions 01/2019
- Guidance on Limited IRB review 01/2019

Continuing Review for Research Predating January 21, 2019

Please contact the STI IRB at irb@stu.edu if approved research predating January, 21,2019 is continuing or in need of approval to discuss specific parameters for completion. **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

The new regulations require changes to the structure and content of informed consent documents predating January 21, 2019. Consent forms must begin with 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 section must be organized in a way

that facilitates understanding. The STU IRB will provide guidance and sample language to assist study teams with this requirement.

New requirements for additional consent elements related to the use of de-identified information, the use of biospecimens, potential for commercial profit and return of clinically relevant results have also been implemented. STU consent form templates have been updated at the STU IRB website to reflect these new elements. The STU IRB will be applying these consent form changes to all federally funded/supported studies and to any study involving greater than minimal risk.

The 2018 regulations require that 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. The posting must occur no more than 60 days after the last study visit by any subject. The specific government website has not yet been named.

STU informed consent templates and examples for the Key Information section have been posted on the STU IRB website (here).

Single IRB Review

Beginning January 25, 2018 all multi-center NIH-funded studies will be required to use single IRB review for the domestic sites. Additional information is posted at: https://grants.nih.gov/policy/clinical-trials/single-irb-policy-multi-site-research.htm

Single IRB review for studies conducted or supported by other federal agencies will be required starting in January 2020.

For assistance, you can email irb@stu.edu.