Common Rule Changes

The U.S. Department of Health and Human Services (HHS) has made changes to the Federal Policy for the Protection of Human Subjects (a.k.a. the "Common Rule") which will go into effect on **January 21, 2019**. The revisions aim to "modernize, simplify, and enhance" oversight for human subjects research in the United States to address changes in the nature of research since the original publication of the Common Rule in 1991. This letter is to inform investigators and research staff of some of the changes that will occur in coming months.

Key Changes:

- **May eliminate continuing review** for most minimal risk research (see below)
- **Expands exemption categories** and changes the review processes
- **Reframes informed consent information** and adds required elements (see attachment)
- **Requires single IRB review** of all federally-sponsored research with multi-institutional collaborators
- **Changes the definition of "vulnerable populations."** Pregnant women and those individuals who are physically handicapped or disabled are no longer included in the definition of vulnerable populations for consenting purposes.

Reminders for Investigators:

- Projects approved on or after January 21, 2019 must be compliant with new rules.
- If a study is approved prior to January 21, 2019 it will remain on the old rule until its next Continuing Renewal. At that point, each study will be reviewed and a decision will be made on a case by case basis as to whether or not continuing renewal will be required. The IRB will notify each Investigator in writing.
- The IRB will not require re-consent for those studies approved prior to January 21, except when other significant changes are made.
- The Common Rule regulations are separate from FDA regulations. The FDA regulations have NOT changed, so FDA still requires annual continuing review for FDA-regulated studies, even those relatively rare Minimal Risk FDA-regulated studies.

What You Can Do:

1. Check our ORO newsletter periodically for new information. Updates regarding the transition will be provided to the SH community, as it becomes available.

2. Look for Lunch & Learn sessions in newsletters, and on our IRB website. **(See below)**
3. Watch for new informed consent templates and guidance that will be released. **(See below)**
4. If you have questions, contact the IRB Office at 616-486-2031 or irbassist@spectrumhealth.org
5. Check the Department of Health and Human Services website for updates to the revised Common Rule:

   https://www.hhs.gov/ohrp/regulations-and-policy/regulations/finalized-revisions-common-rule/index.html

*****Please visit forms and policies page to find the Informed Consent Form Template. This has been updated to comply with the New Common Rule and includes an updated HIPAA Authorization Section. Please begin utilizing the clean version of the template for all new studies.**

More information to come!