SU's Statement

Starting January 21st, Salisbury University's Office of Graduate Studies and Research and SU's IRB will be implementing the new Common Rule changes for human subject research protection. The Office of Graduate Studies and Research wanted to provide SU's faculty, staff, and student researchers information about these changes.

Common Rule Changes

On January 19, 2017, the Department of Health and Human Services (DHHS) and supporting federal agencies issued revisions to the regulations for human subject research; most commonly known as The Common Rule. Most of these changes will be in effect on January 21, 2019.

Why were these changes implemented by DHHS?

The goal of these revisions is to better protect research subjects and to reduce administrative burdens for low-risk research. The goal is to allow "more flexibility in keeping with today's dynamic research environment" (OHRP, 2018).

The Office of Human Research Protections (OHRP) has made available information on the new rule at: https://www.hhs.gov/ohrp/regulations-and-policy/regulations/finalized-revisions-common-rule/index.html

What does this mean for research at SU?

Most of the Common Rule changes relate directly to IRB function, but there are a few changes that will directly impact researchers.

Informed Consent. With the new regulations, there will be changes to the structure and content of the informed consent. The new regulations **require** that the consent forms begin with a concise summary of the "key information" of the study that meets the "reasonable person standard." This information must provide prospective subjects the information about the study, and why one might or might not want to participate in the research.

The "key information" suggestions include:

a) Why consent is being sought and participation is voluntary
b) Purpose of the Study
c) Expected duration of the study
d) Procedures to be followed as part of the research
e) Potential Risk or Discomforts for research participants
f) Potential Benefits for participation
g) Appropriate alternative procedures or courses of treatment, if any that may be advantageous to the prospective subject.

The "reasonable person standard" requires that subjects be provided with the study's key information and be organized and discussed in a way that aids in comprehension.

a) Readability levels of consent materials must be provided to the IRB.

Electronic Signatures. Electronic signatures are now allowed for documentation of consent provided that a written copy of the consent form (acceptable as electronic formats) is given to the person signing the consent form.

Studies for Clinical Trials. Informed consents for clinical trials (studies assigning participants to 1 or more research interventions) will also be required to be posted on a federal website (ClinicalTrials.gov) within 60 days of participant enrollment closing.

New Exempt Categories. There are 3 levels of review: exempt, expedited, and full committee review. The new Common Rule has broadened the type of research with adults that can be considered exempt. Submission to the IRB office for exempt determination is still required.

Continuing Review: Minimal Risk studies reviewed by the IRB after January 21st, 2019 via the expedited procedure will no longer require annual continuing review under the new rule. Please note, this is for studies receiving expedited approval after 1/21/19. Requirements to request amendments or to report safety events to the IRB have not changed.

Single IRB Review: This Common Rule change will not be implemented until January 19th, 2020. This requirement will allow multi-institutional research studies to have a single IRB review. More information will be provided in the future.

Broad Consent. The new common rule changes also allow for researchers to seek "broad consent" from research participants. This relates to storage of identifiable information or biospecimens for possible future secondary use. Institutions are currently given the option to initiate or not the "broad consent" policy. Salisbury University's IRB is not approving "broad consent" at this time pending additional Office of Human Research Protections guidelines on storage and management of the consent.

Current Research Protocols at SU. For research protocols approved prior to January 21, 2019. Researchers will not be required to make any changes to their current research. SU's IRB will operate under the two guideline standard. SU's IRB will offer guidance to researchers who may request transition to the new guidelines. Transition to the new Common Rule guidelines may require re-consenting of subjects and additional IRB review.

For More Information. SU's IRB will keep faculty, staff, and student researchers updated on protocol changes based on the new Common Rule regulations. As further guidance is issued from the Office of Human Research Protections is provided, SU's IRB will update. SU researchers are also encouraged to contact the Office of Graduate Studies and Research and the IRB with any additional questions.