LOUISIANA TECH
UNIVERSITY

INTEROFFICE MEMORANDUM

TO: FACULTY RESEARCHERS

FROM: RICHARD KORDAL AND GARY STOKLEY, CO-CHAIRS HUC/IRB

SUBJECT: REVISED COMMON RULE (45 CFR 46 – PROTECTION OF HUMAN SUBJECTS)

DATE: 3/1/2019

CC:

In 1991, the Common Rule (45 CFR 690) for the Protection of Human Subjects was published in the Federal Register and became law. The "Common Rule" as it is usually abbreviated, is a set of regulations establishing baseline conduct for research ethics involving human subjects. In the years following its promulgation there have been significant technical advances that have changed the scope of human subject research (e.g., mapping of human genome). Therefore, beginning in 2011 the government initiated the process of modernizing it. Some of the goals were to remove any ambiguity in the 1991 Rule, reduce the regulatory burden on institutions and IRBs, provide better protection to human subjects involved in research studies and facilitate research projects. After six years of deliberations and public comments, a new revised Common Rule (45 CFR 46) was published on January 19, 2017. It was originally given an effective date of January 19, 2018, but this date was delayed twice to allow institutions more time to become familiar with the material and prepare for the changes. Now after 2 delays, it has gone into effect as of January 20, 2019.

As highlighted below, there have been several significant changes in the new regulations, most of which are viewed positively by practitioners.

1) **Definition of Research**. Four sets of activities are now "excluded" from the definition of research: a) scholarly and journalistic activities that focus on a specific individual (e.g., oral history), b) public health surveillance activities conducted by a public health authority, c) information that is collected for criminal justice purposes, and d) operational activities conducted for national security purposes.

2) **Exempt Research**. The categories of exempt research have been expanded from 6 to 8 and revised. Some of these may require a new level of "limited review."

3) **Continuing Review**. Projects that have been deemed to be of minimal risk and have undergone expedited review will no longer require annual continuing review provided there have been no changes to the protocol.

4) **Cooperative Research**. Institutions involved in cooperative research projects may rely on a single IRB.

5) **IRB Approval**. IRB approval is no longer needed at the grant application or proposal stage. However, the IRB must review and approve such research (e.g., research protocol) upon awarding of the grant and before initiation of the project. For more information on this matter, please refer to guidance from OHRP: https://www.hhs.gov/ohrp/regulations-and-policy/requests-for-comments/draft-guidance-elimination-of-irb-review-of-research-applications-and-proposals/index.html, and/or from NIH: https://grants.nih.gov/grants/guide/notice-files/NOT-OD-19-055.html.

For more details on these and other changes to the Common Rule please visit the Office for Human Research Protections (OHRP) website: https://www.hhs.gov/ohrp/. Additional training is available through the CITI Program online course entitled "Revised Common Rule" which consists of 10 modules.

Louisiana Tech University HUC/IRB changes in response to new Common Rule

1) For those projects supported by an outside sponsor, the PI must fill-out and submit the IRB online form at the time of the grant award, and must receive approval before initiation of any studies. For self-funded or internal (La Tech) supported projects, the PI must fill-out and submit the IRB online form and receive approval before initiation of any studies.

2) Those projects that meet the "exemption" category as deemed by the IRB may be placed in the "limited IRB review" or "expedited" category, and will be reviewed accordingly.

3) Those projects deemed more than minimal risk to subjects will still be reviewed at a scheduled full IRB Committee meeting.

4) Those projects that do not meet the definition of "research" may not need to be submitted to the IRB for review and approval, but the PI should check with the IRB and/or our checklist before making that decision.