Revisions to Human Subjects Research Regulations

The Office for Human Research Protections has assigned January 21, 2019 as the date with which institutions must be in compliance with the revised regulations for the protection of human research subjects (45 CFR 46). Lindenwood University has revised applicable policies and procedures to ensure compliance with these new requirements.

The LU IRB will transition research involving human subjects to this new policy as follows:

- Research approved prior to January 21, 2019, will follow the pre-2018 regulations
- Research approved after January 21, 2019, will follow the 2018 regulations
- Research approved under the pre-2018 regulations may be required to be updated for compliance with the 2018 regulations should the IRB consider it necessary.

Here is a brief summary of these changes and how they may affect your research:

1. New Exempt Categories

One of the most significant changes in the revised regulations will affect researchers at Lindenwood University. The Exempt Categories for research represent specific types of minimal risk research meeting the conditions of a specified category, which allow for streamlined application and review by an Institutional Review Board (IRB). These revisions will affect the way the LU IRB reviews certain types of minimal risk research, in many cases allowing for greater flexibility around what may be considered Exempt. These new regulations will be reflected in the Approval Letter for all Exempt studies.

Please refer to the comprehensive *Exempt Category Revision Guide* for detailed information on how these changes may impact your research.

2. New Continuing Review Requirements

The new regulations do not require Continuing Review for Research reviewed and approved by Expedited procedure. An IRB may now determine on a case-by-case basis which minimal risk research requires Continuing Review. The LU IRB, however, will continue to require Continuing Review for research reviewed by Expedited procedure to ensure the needs of researchers and research participants are being met in the context of these protocols.

3. New Consent Form Requirements

The new regulations require several changes to Informed Consent Documents, including the presence of "*a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research*." Lindenwood University has been in compliance with this requirement since the last cycle of revisions to the Informed Consent Templates, which is why it is critical that investigators use the most current version of these templates while constructing consent documents.

4. New Single IRB Mandate

A final issue to consider affects Lindenwood University in a more limited way, but will be felt as a significant change when LU researchers collaborate with federally-funded research initiated at other institutions. In the old model, the IRB at each institution in a collaborative research project would review the research being conducted at their site. In this new model, one institution must be designated as the IRB of record for all institutions involved. Each institution then has a more limited role in administratively processing the research locally. IRBs are required to be in full compliance with this new mandate on January 19, 2020.