

## **INSTITUTIONAL REVIEW BOARD – NORTHWESTERN STATE UNIVERSITY**

### **SUMMARY OF CHANGES FROM PRE-2019 RULE TO 2019 RULE**

Below is a summary of the changes that will be made to the NSULA IRB application process. There are two main types of changes: (1) changes to the federal rule – from the Common Rule to the Final Rule, and (2) changes made by the institution IRB to update and facilitate the review process.

All these changes will be implemented on January 21<sup>st</sup>, 2019 and will be reflected in all the associated documents and links on the [www.nsula.edu/irb](http://www.nsula.edu/irb) website including the Policies and Procedures Manual.

#### **Changes to the Federal Rule – Implementing the Final Rule:**

- Some modifications to the informed consent forms in order to be clearer to the participant. A major change is to have bullet points in the beginning of all the important and relevant information. This is typically for “long” consent forms; however it will be beneficial for all forms. The sample informed consent document that will be posted on the [www.nsula.edu/irb](http://www.nsula.edu/irb) website will reflect these changes.
- Some research that was considered Expedited under the Common Rule, but poses minimal risk, can now be considered Exempt under the New Final Rule with a limited review; for example, if the data is collected with identifiers it can now be considered Exempt with a limited review of the privacy and confidentiality issues only. The limited review will be conducted by 1 voting member of the IRB other than the Chair.
- The Exempt category (3) has completely changed and will now allow “for the intervention to be distinct from the data collection method; for example, a research study comparing test performance of test takers in quiet or noisy surroundings would qualify for this exemption. Also subjects could be asked to perform cognitive tasks, and audiovisual recording could be used to collect the data, without any educational test, survey or interview procedure occurring, and this research would qualify for this exemption.”
- Eliminates the requirement for continuing review of Expedited research. This will not be applied for research that was approved under the pre-2019 rule. If an Expedited study was approved before the Final Rule implementation and needs continuing review, it will need to re-apply under the new Final Rule guidelines; and therefore, become transferred to the new Final Rule.
- Any IRB application that was submitted before January 21<sup>st</sup>, 2019 will be processed under the pre-2019 Common Rule and will therefore NOT be transferred to the new Final Rule (unless it falls under the above category of an Expedited study that requires continuing review).

#### **Changes made by the NSULA IRB. All were approved by majority of a quorum during the full IRB meeting on December 5<sup>th</sup>, 2018:**

- The application process will change to a digital submission process. All required forms and documents will be available on the [www.nsula.edu/irb](http://www.nsula.edu/irb) website and will be in a fillable pdf format. The entire application will be submitted electronically to [irb@nsula.edu](mailto:irb@nsula.edu) All the documents should be saved separately, however, they should all be included in one email. All required signatures will be done electronically.

- The ethics training certificate will be conducted by the CITI program. There will be separate training programs for student researchers, faculty researchers, and IRB members. We are establishing a university-wide relationship with the CITI program so any course that requires ethics training should also use the CITI training.
- There will be a 5-year time limit for ANY ethics training certificate. The ethics training certificate of any individual involved in the research project must be recent. Specifically, the ethics training must have been completed within the last 5 years. If not, then the researcher needs to get re-certified. This includes faculty sponsors. From now on, there will be a 5-year expiration for any and all ethics training certificate.
- Faculty sponsors of student research application will need to include their own checklist of the application materials along with the submission.

If you have questions or would like more information, please email the IRB Chair at [karamzanderst@nsula.edu](mailto:karamzanderst@nsula.edu)

*\*quotations are from the Office of the Federal Register*