New Rule Coming!

As the IRB wants you to be aware of the changes that are coming in the future, we have provided a summary of the major changes on our website.

Please be aware that in June 2018, notice was provided that implementation of the New Rule has been delayed until January 2019. As we obtain more information, including guidance concerning these updated rules, we will update our website and hold informational sessions to provide more detailed information to ETSU researchers. Please contact Janine Olive at olivef@etsu.edu with questions about the new rules.

The current rules that govern federally funded human subject research (Common Rule) have been in place since 1991. The process to update those rules began several years ago in 2011. An update was issued in 2017 and was to become effective earlier this year. However, the implementation date for the update has been pushed back until January 2019. The most recent postponement does include a provision for implementation of three provisions in the interim, but ETSU has decided to not implement this New Rule in stages, as doing so is likely to increase confusion and complexity.

For the full text of the Federal Register April 2018 notice, click here.

For the full text of the Revised Common Rule, click here.

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ETSU Biosafety Review

ETSU Policy 23 was revised recently to include addressing types of studies that require review by the ETSU Institutional BioSafety and Chemical Safety Committee (IBC) or additional training.

Please be aware that if your ETSU study involves any of the following, review by the IBC is required:

a. shipping specimens
b. transporting of specimens (e.g., from collection site to ETSU, in any area of public access, or in between building on campus)
c. collection of specimens in non-clinical setting
d. administration of live vaccine(s)
e. exposure of researcher(s) or participants to toxic or hazardous chemicals (as defined by ETSU Biosafety) during procedures done for research purposes.
f. administration of vaccines using recombinant nucleic acid

Also, if your study involves blood draws by study staff, the IRB requirement is that those study staff who will be drawing the blood must either be a licensed or certified health care provider where this procedure falls within the scope of their practice, or have certification or other written documentation of appropriate phlebotomy training. In addition, an initial IRB approval will not be issued for ETSU studies unless bloodborne pathogen training has been verified for study staff who are drawing blood (by the IBC if the study requires their review or by IRB staff if IBC review is not required). For more information, see IRB Policy 23.

EAST TENNESSEE STATE UNIVERSITY