



Revised Policies

The ETSU and ETSU/VA IRB approved multiple policy revisions at their May 2018 meetings.

Some of the revisions were minor administrative changes, but many of the revisions were related to upcoming changes in the Common Rule. A [summary of the changes](#) is posted as a reference.

We have created [a website](#) to provide you information about the changes.

The process to make changes to the 1991 Common Rule began several years ago in 2011. A Final Rule making the long-awaited changes was published in January 2017, with most provisions to be effective in January 2018. In January 2018, an Interim Final Rule was published, delaying the New Rule until July 2018.

In April 2018, a Proposed Rule was published, seeking public comment on whether the New Rule should be further delayed, until January 2019. The Proposed Rule also introduced the possibility of allowing some of the New Rule to be implemented in July 2019, while delaying the rest of the New Rule.

At this time, it is unclear whether none, some or all (except Single Site IRB review) of the New Rule will go into effect on July 19, 2018.

Please note that the Food and Drug Administration (FDA) has its own rules, and no changes have been published about FDA rules. That means that none of these changes apply to research subject to FDA rules.

The revised policies have several sections, such as “For studies under the Current Rule” and “For studies under the New Rule”. No studies are under the New Rule at this time. None of the New Rule goes into effect,

New Rule

As we obtain more information, including dates of implementation and much-awaited OHRP guidance concerning the New Rule, we will hold informational sessions to provide more detailed information to our researchers.

For the full text of the Federal Register April 2018 notice, [click here](#).

For the full text of the Revised Common Rule, [click here](#).

Contact us at 423-439-6053 if you have any questions or concerns about the new regulations, or email us at olivef@etsu.edu.

