



IRB News

Office for the Protection of Human Research Subjects

January 2021, Page 1

NEW! Consent Templates

The ETSU IRB informed consent templates were revised effective 9/14/2020 and are available on the IRB website [here](#). All new studies must use the most recent template version when submitting to the IRB for review. The sections on compensation for research-related injury; payment to subjects; and IRB contact information must be included verbatim for all research occurring at ETSU. Other template language must be included as applicable and may be edited to improve readability for the specific study population.

FERPA & Human Subjects Research

The HRPP remains committed to protecting the rights and welfare of students and research participants. Researchers who conduct research with students as participants and/or using students' education data, whether in a K-12 or higher education setting, must comply with FERPA (Family Educational Rights and Privacy Act). Accessing student records requires either written consent or be eligible for a FERPA exception. The consent form needs to state which educational records are being accessed or collected for research purposes.

FERPA cannot be waived. Unless an exception applies, written consent is necessary to release identifiable FERPA information. If a researcher wants to conduct research using ETSU student data without informed consent, they must contact Lisa Williams, ETSU Associate Counsel to determine if the research qualifies for an exception. Likewise, research in K-12 settings requires documentation from the appropriate school official regarding FERPA compliance. The ETSU IRB needs a copy of this correspondence to facilitate the IRB review.

Transition to New Rule Continues

The New Common Rule (which governs IRBs) has been fully implemented at ETSU, and now we are working towards transitioning eligible research to the New Rule. More information about the Common Rule changes and how those were implemented at ETSU is available on the IRB [website](#). Research originally approved prior to January 1, 2019 were approved under the "Old Rule" and are grandfathered under those regulatory requirements. ETSU can voluntarily transition research to the New Rule requirements and has begun that process to take advantage of the reduced administrative burden afforded by the New Rule changes.

Eligible studies will be transitioned on a study-by-study basis during the routine continuing review process, and questions have been incorporated into the Continuing Review xform to facilitate the transition process, which may involve revisions to the informed consent to meet New Rule requirements. Studies transitioned to the New Rule may not require annual continuing review and will instead submit a brief annual Administrative Check-in.

Research Training

As a reminder for all investigators and study staff, the ETSU IRB requires completion of research training through the CITI online training platform. Training must be completed prior to the IRB approval of any new studies and must be maintained for as long as the study is active. CITI training expires every 3 years and must be renewed as long as a researcher is study staff on an active IRB study. Visit our website [here](#) for more information about training requirements.



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