



IRBNews

Office for the Protection of Human Research Subjects

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Updated Consent Templates

The ETSU IRB informed consent templates were revised effective 4/2/21 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.

New Question added to Admin Check-in about COVID-19

Beginning March 2021, a new question is presented on the annual Administrative Check-in xform for researchers to report any changes made to their research throughout the year in response to COVID-19. The ETSU Human Research Protection Program understands that the pandemic presented unforeseen challenges for researchers that may have required modifications or changes to the research procedures in some way.

As IRB policy requires that researchers report all changes to research and receive prior approval, the new question will be another way to help ensure that our researchers report those changes and receive IRB approval. The new question will be on the forms for approximately one year.

More information about post-approval requirements for IRB review are available on the website. Please note that all active research must still follow ETSU guidelines for safety precautions when conducting research during the ongoing pandemic, which is available [here](#).

VA Reporting Requirements

VA researchers should be aware that the VA has specific requirements for research and reporting that may vary from ETSU requirements. VA researchers and employees must abide by all VA rules and requirements during the conduct of VA research. The VHA Directive 1058.01, revised October 2020, included many changes to the reporting requirements for research related to unanticipated problems, adverse events, and noncompliance.

Any questions about the current requirements for VA researchers should be directed to the VA Research and Development office. The ETSU IRB Policies and Procedures have been revised to incorporate the new VA reporting requirements and are available [here](#).

IRB Study Closures

As a reminder for all investigators, the ETSU IRB requires that the IRB be notified when studies are complete. If your IRB-approved study has completed all interactions with human subjects and/or their identifiable data/records, it can likely be closed. After all data is collected and de-identified, the IRB file can be closed – even if researchers are still analyzing the data and producing research reports.

Please note that investigators should also close their studies before they separate from ETSU, such as graduating students or those ending employment. ETSU IRB policy requires that Principal Investigators be affiliated with ETSU in order to conduct research on behalf of ETSU. Thus, if PI's are no longer affiliated with ETSU, the study should be closed with the ETSU IRB.

[Study closures](#) may be submitted via the Admin Check-in or Continuing Review/Study Closure xforms.



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