

IRBNews



Office for the Protection of Human Research Subjects

May 2016

HIPAA Policy Changes

The ETSU/VA IRB recently approved HIPAA Policy Revisions. See Policy 14 for details.

I. **Applicability of HIPAA:** HIPAA applies to research studies that use, create, or disclose PHI. In general, there are two ways a research study involves PHI:

- A. The study involves review or use of medical records or individually identifiable information held by a covered entity as a source of research information. Retrospective studies may involve PHI in this way, as well as prospective studies when a researcher intends to contact a participant's healthcare provider to obtain PHI or to verify information reported by the participant.
- B. The study creates new medical records in conjunction with the provision of healthcare as part of the research study.

II. **New Training Requirement:** Beginning August 1, 2016, verification of completion of HIPAA training is required for all study staff on studies covered by HIPAA. For both initial review and continuing review, IRB approval will not be issued until current HIPAA training is verified for all study staff.

If PHI belonging to ETSU/ETSU Quillen Physicians will be accessed as part of the study, study staff must complete ETSU's HIPAA training.

If PHI belonging to the VA will be accessed as part of the study, study staff must complete VA's HIPAA training.

ETSU training access:

<https://healthsafety.etsu.edu/index/login>

If HIPAA training is not listed under "modules you need to take" or you do not have an ETSU account, please contact Linda Zerby @ zerbyl@etsu.edu

Researcher Responsibilities:

Please read Policy 14 for other revisions and to and review your responsibilities as a researcher under HIPAA rules.



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