Health Insurance Portability and Accountability Act (HIPAA)

The Health Insurance Portability and Accountability Act (HIPAA), also referred to as the Privacy Rule, at 45 CFR parts 160 and 164, establishes a category of health information, defined as protected health information (PHI), which a covered entity may only use or disclose to others in certain circumstances and under certain conditions.

In general, the Privacy Rule requires an individual to provide his/her signed permission, known as an Authorization, under section 164.508 of the Privacy Rule, before a covered entity can use or disclose the individual's PHI for research purposes.

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Under certain circumstances, however, the Privacy Rule permits a covered entity to use or disclose PHI for research without an individual's Authorization. One way a covered entity can use or disclose PHI for research without an Authorization is by obtaining proper documentation of a waiver of the Authorization requirement by the IRB, or another type of review body, known as a Privacy Board. The ETSU/VA IRB shall serve as the Privacy Board.

Pre-Screening Activities: ETSU is permitted to use or disclose PHI for reviews preparatory to research with representations from the researcher that satisfy the Privacy Rule. As an example, this review might be used to allow a researcher to determine the feasibility of conducting a study.

In order for ETSU to permit a researcher to conduct a review preparatory to research, ETSU must receive the following representations from the researcher:

⇒ that the use or disclosure is sought solely to review PHI as necessary to prepare a research protocol or for similar purposes preparatory to research,

⇒ that the researcher will not remove any PHI from ETSU,

⇒ that the PHI that the researcher seeks to use or access is necessary for the research purpose.

VA: VA studies that require a HIPAA Authorization and that obtained initial IRB approval after March 31, 2011 require a standalone HIPAA Authorization.

For studies approved after March 12, 2015, the VA Form 10-0493, Authorization for Use and Release of Individually Identifiable Health Information for VHA Research, must be used to document the authorization.

The 10-0493 authorization:

⇒ May not be embedded in the consent form
⇒ May not contain information that contradicts any provisions of the protocol, the informed consent, or other documents submitted for IRB approval

⇒ Must list all potential disclosures to a non-VA entity

For VA research that requires a HIPAA Authorization, the IRB VA Checklist Reviewer will verify receipt of the separate HIPAA authorization that was reviewed and approved by the VA Privacy Officer and ensure that it is consistent with the informed consent document and protocol.

VA researchers are required to maintain the signed HIPAA Authorization in accordance with VHA’s Record Control Schedule 10-1 (RCS 10-1).

**Direct Identifiers (18 HIPAA Identifiers):** When developing research protocols, the Investigator must take into consideration allowable use and disclosure of PHI under HIPAA. The following identifiers are considered links to a particular individual or data that could enable individual identification:

1. names;
2. geographic subdivisions smaller than a State, including street address, city, county, precinct, ZIP code, and their equivalent geocodes, except for the initial three digits of a ZIP code;
3. all elements of dates (except year) for dates directly related to an individual (e.g., date of birth, admission);
4. telephone numbers;
5. fax numbers;
6. electronic mail addresses;
7. social security numbers;
8. medical record numbers;
9. health plan beneficiary numbers;
10. account numbers;
11. certificate/license numbers;
12. vehicle identifiers and serial numbers, including license plate numbers;
13. device identifiers and serial numbers;
14. web universal locators (URL’s);
15. internet protocol (IP) address numbers;
16. biometric identifiers, including finger and voiceprints;

17. full-face photographic image and any comparable images; and

18. any other unique identifying number, characteristic, or code.

**IRB Authority:** The IRB has the authority to approve a waiver or an alteration of the Privacy Rule’s Authorization requirement in addition to the traditional IRB authorities to protect research participants from risks under 45 CFR part 46 (Department of Health and Human Services (HHS) Regulations for the Protection of Human Subjects) 38 CFR 16, and 21 CFR parts 50 and 56 (Food and Drug Administration (FDA) Regulations on Protection of Human Subjects). Other Federal and State laws and regulations may impose other or additional restrictions and limitations on the use of health information for research that may not be waived or altered by an IRB (or Privacy Board) under the authority granted to it by the Privacy Rule. The IRB and the OPHRS shall enforce the mandates of the Privacy Rule pursuant to the requirements necessary for the protection of the subject and/or their protected health information as applicable to the research.

**Training:** Training on the requirements imposed by the Privacy Act and other information regarding HIPAA, including guidance, forms and continuing education, will be made available to researchers online.