IRB Policy 14: HIPAA Policy
Revision Date: May 15, 2007, revised May 25, 2016, revised January 24, 2019, revised January 24, 2020, March 2, 2021

I. Pertinent Definitions:

Terms used in this policy and not otherwise defined shall have the same meaning of those terms in the HIPAA Rules.

1) **Covered Entity** means: (1) A health plan; (2) A health care clearinghouse; or (3) A health care provider who transmits any health information in electronic form in connection with a transaction covered by HIPAA.
2) **Data Use Agreement** is an agreement into which the covered entity enters with the intended recipient of a limited data set that establishes the ways in which the information in the limited data set may be used and how it will be protected.
3) **Disclosure** means the release, transfer, provision of access to, or divulging in any manner of information outside the entity holding the information (For ETSU, outside of a single ETSU healthcare component).
4) **Individually Identifiable Health Information** is information that is a subset of health information, including demographic information collected from an individual, and: (1) Is created or received by a health care provider, health plan, employer, or health care clearinghouse; and (2) Relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual; and (i) That identifies the individual; or (ii) With respect to which there is a reasonable basis to believe the information can be used to identify the individual.
5) **Limited Data Set** refers to protected health information that excludes 16 categories of direct identifiers and may be used or disclosed, for purposes of research, public health, or health care operations, without obtaining either an individual's Authorization or a waiver or an alteration of Authorization for its use and disclosure, with a data use agreement.
6) **Protected health information (PHI)** is all individually identifiable information held or transmitted, in any form or medium (i.e. electronic, paper, or oral) by a covered entity or its business associate.
7) **Use** means, with respect to individually identifiable information, the sharing, employment, application, utilization, examination or analysis of such information within an entity that maintains such information.
8) **Research** means a systematic investigation including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

II. 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:

1) 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.
2) The study creates new medical records in conjunction with the provision of healthcare as part of the research study.

III. Required HIPAA Training

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. HIPAA training is required on an annual basis.

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.

For initial and continuing review of studies where ETSU/ ETSU Quillen Physicians PHI is being accessed, IRB IRT or Coordinator will verify current HIPAA training for the study staff. For VA studies, the VA is responsible for verifying that all study staff have or will have current HIPAA training per institutional requirements before issuing VA study approval.

In addition, if a modification is being submitted to add a study staff member on a study subject to HIPAA, for studies where ETSU/ ETSU Quillen Physicians PHI is being accessed, IRB Coordinator will verify current HIPAA training for the proposed new staff prior to approval of the modification. For VA studies, the VA is responsible for verifying that all study staff have or will have current HIPAA training per institutional requirements before issuing VA study approval.

IV. Use and Disclosure of PHI for Research *with* Individual Authorization

The HIPAA Privacy Rule establishes the conditions under which PHI may be used or disclosed by a covered entity for research purposes.

In general, the HIPAA Privacy Rule requires that a researcher obtain authorization from the research participant to use or disclose PHI about himself or herself for research. For an authorization to be valid, it must be written in plain language and include the following:

1. A description of the information to be used or disclosed that identifies the information in a specific and meaningful fashion;
2. The name or other specific identification of the person(s), or class of persons, authorized to make the requested use or disclosure;
3. The name or other specific identification of the person(s), or class of persons, to whom the covered entity may make the requested use or disclosure;
4. A description of each purpose of the requested use or disclosure;
5. An expiration date or an expiration event that relates to the individual or the purpose of the use or disclosure. (The statement “end of the research study,” “none,” or similar language is sufficient if the authorization is for a use or disclosure of protected health information for research, including for the creation and maintenance of a research database or research repository.) Unlike other authorizations, an authorization for a research purpose may state that the authorization does not expire, that there is no expiration date or event, or that the authorization continues until the “end of the research study”;
6. Signature of the individual and date. If the authorization is signed by a personal representative of the individual, a description of such representative's authority to act for the individual must also be provided;
7. Statement of the individual's right to revoke the authorization in writing;
8. A description of the exceptions to the right to revoke and a description of how the individual may revoke the authorization;
9. The ability or inability to condition treatment, payment, enrollment or eligibility for benefits on the authorization; and
10. A statement of the potential for information disclosed pursuant to the authorization to be subject to redisclosure by the recipient and no longer be protected by the authorization.

Conditioned Authorizations

Conditioned means that an authorization “conditions” treatment, payment, enrollment in a health plan or eligibility for benefits on an individual signing an authorization form. Under HIPAA, this is generally not allowed. However, HIPAA allows an exception for research. A researcher is allowed to exclude an individual from a study that involves research-related treatment if the person refuses to authorize the use/disclosure of their PHI.

An authorization for a research study can contain both conditioned and unconditioned portions. The authorization must clearly distinguish between what elements are conditioned and what elements are unconditioned. The authorization must also be structured so that a participant is clearly allowed the option to take

part in the unconditioned research components. An example is a clinical trial which also involves an optional pharmacokinetics (PK) study.

Participating in the clinical trial is conditioned upon the individual providing an authorization to allow use/disclosure of their PHI. Participating in the PK study is optional; a participant can choose to decline this portion and still be in the clinical trial itself.

Researchers should design such authorizations (called "compound" authorizations) so that participants "opt in" to the optional part of the study (for example, by using checkboxes). Authorizations may not simply allow an individual to opt out because the opt out approach does not provide an individual with a clear way to authorize the optional component (e.g. an authorization is not allowed to say "check here if you do not want your data to be used in the PK study").

Some exceptions: Compound authorizations may not be used for research that involves the use or disclosure of psychotherapy notes. An authorization for use or disclosure of psychotherapy notes may not be combined with other authorizations.

Future Research
An authorization may be obtained from an individual for uses and disclosures of protected health information for future research purposes, so long as the authorization adequately describes the future research such that it would be reasonable for the individual to expect that his or her protected health information could be used or disclosed for the future research purposes.

Non-VA studies
For non-VA studies, the written authorization must be embedded in the research informed consent document. Researchers should use the ETSU ICD with HIPAA Authorization template (available on the website, www.etsu.edu/irb) in order to ensure that all elements required by the Privacy Rule are present. If any other template is used, then the HIPAA Authorization must undergo review by the HIPAA Compliance Officer to ensure the presence of all required elements. Final IRB approval will be held until this review is complete. An authorization that does not contain all the required elements is not considered to be a valid authorization.

VA studies
For VA studies, PHI obtained in research for which the IRB of Record or Privacy Board has waived the requirements to obtain a HIPAA authorization may not be disclosed outside VA unless the VA facility Privacy Officer (PO) ensures and documents VA's authority to disclose the PHI to another institution (i.e. Material Transfer Agreement, Data Use Agreement). A waiver of HIPAA authorization by itself is not sufficient to fulfill the requirements of other applicable privacy regulations and statutes such as the Privacy Act of 1974 (5 U.S.C. 552a).

In accordance with the HIPAA Privacy Rule at 45 CFR 164.508, a written

authorization signed by the individual to whom the information or record pertains is required when VA medical facilities need to access, collect, develop, use, or disclose individually identifiable health information for a purpose other than treatment, payment, or health care operations (e.g., research) unless there is legal authority (e.g., waiver, limited data set with data use agreement, etc.) to use and/or disclose such information (see VHA Directive 1605.01).

1. The written HIPAA authorization may either be a standalone document or combined with the research informed consent approved by the IRB. If a standalone document is used as the written HIPAA authorization, VA Form 10-0493: Authorization for Use and Release of Individually Identifiable Health Information Collected for VHA Research must be used (See VHA Directive 1200.05 §23.a(1)).
2. All potential disclosures to a non-VHA entity must be listed within the written authorization
3. The PO must review the written HIPAA authorization to ensure it contains all required elements and is consistent with all privacy requirements before the PI can begin to use or collect the individual's information based on an approved research protocol (see VHA Directive 1605.01)
4. Data disclosed under a properly executed written HIPAA authorization must be securely transferred according to VA information security requirements.

For VA research that requires a standalone 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.

V. Use and Disclosure of PHI for Research *without* individual authorization:

In general, the HIPAA Privacy Rule requires that a researcher obtain authorization from the research participant to use or disclose PHI about him or herself for research. However, under certain circumstances, the Privacy Rule permits a covered entity to use or disclose PHI for research without an individual's authorization. To use or disclose PHI without the participant's authorization, the researcher must obtain one of the following:

1) Documented Institutional Review Board (IRB) or Privacy Board Approval of Alteration or Waiver of Research Participant's Authorization:

A covered entity is permitted to use or disclose PHI for research without individual authorization pursuant to an alteration or waiver of authorization by the ETSU/VA IRB. To request alteration or waiver of the HIPAA authorization requirement, researchers must complete the "Request for HIPAA Alteration or Waiver" section of the New Protocol Submission xform. In that section, the PI is responsible for

clearly and thoroughly explaining the following:

1. Why the research could not practicably be conducted without the waiver or alteration;
2. Why the research could not be practicably conducted without access to and use of the PHI;
3. A list of the PHI to be collected/used/disclosed and a list of the source(s) used/accessed for the PHI;
4. An explanation of how the PHI is limited to the minimum necessary to accomplish the stated research purpose;
5. Why the use or disclosure of PHI involves no more than a minimal risk to the privacy of individuals;
6. A description of the plan to protect identifiers, including where PHI will be stored and who will have access;
7. A description of the plan to destroy the identifiers as quickly as possible; and
8. A description of the plan to track disclosures.

The PI must also provide written assurances that the PHI will not be re- used or disclosed except as required by law, for authorized oversight of the research, or for other research for which the use or disclosure of PHI would be permitted by HIPAA.

The ETSU/VA IRB must determine that the following criteria are met before the board approves the request for alteration or waiver of the HIPAA authorization requirement:

i. The use or disclosure of PHI involves no more than minimal risk to the privacy of the individuals, based on, at least, the presence of the following:
    a. An adequate plan to protect the identifiers from improper use and disclosure;
    b. An adequate plan to destroy the identifiers at the earliest opportunity consistent with the conduct of the research unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and
    c. Adequate written assurances that PHI will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of PHI would be permitted by HIPAA;
ii. The research could not practicably be conducted without the waiver or alteration; and
iii. The research could not practicably be conducted without access to and use of the PHI.

The ETSU/VA IRB is responsible for reviewing a request to waive or alter consent separately from reviewing a request for alteration or waiver of the HIPAA

authorization requirement. As the criteria for alteration or waiver of the HIPAA authorization requirement are very similar to those for waiving informed consent, if the research study includes the obtaining of written informed consent, the study will be unlikely to meet the requirements outlined above (other than a partial waiver for recruitment; see section “Partial Waivers” for related information).

The ETSU/VA IRB may use expedited processes to review a request for alteration or waiver of the HIPAA authorization requirement if the research activity is determined to involve no more than minimal risk (including risk to the privacy of the individual) and meets established categories for expedited review (see Expedited Policy VIII).

Documentation of approval of the request for alteration or waiver of the HIPAA authorization requirement will be provided in IRBManager so that it is available to researchers. The approval of the request for alteration or waiver of the HIPAA authorization requirement will include:

i. The identity of the IRB or Privacy Board;
ii. The date on which the alteration or waiver of authorization was approved;
iii. A statement that the IRB or Privacy Board has determined that all the specified criteria for a waiver or alteration (see section above) have been met;
iv. A brief description of the PHI for which use or access has been determined to be necessary by the IRB or privacy board;
v. A statement that the alternation or waiver of authorization has been reviewed and approved under normal (full) or expedited review procedures; and
vi. The signature of the Chair or the Chair’s designee.

Partial Waivers or Alterations

For uses and disclosures of PHI for research purposes, the ETSU/VA IRB may approve a waiver or alteration of the HIPAA authorization requirement in whole or in part. A complete waiver occurs when the ETSU/VA IRB determines that no HIPAA authorization is required for the covered entity to use or disclose PHI for the research study. A partial waiver occurs when the ETSU/VA IRB determines that the covered entity does not need authorization for all PHI uses or disclosures for research purposes, such as disclosing PHI for research recruitment. When the ETSU/VA IRB grants a partial waiver of recruitment, this does not mean that the requirement that a participant provide a HIPAA authorization for other portions of the study has been waived.

The ETSU/VA IRB may also approve a request that removes or alters some of the required elements of a HIPAA authorization. This is called an “alteration.”

Disclosures

Disclosures of PHI that are made in connection with research conducted under a waiver of HIPAA authorization must be tracked. This is required in order to allow

the covered entity to respond to individuals who request an accounting of disclosures of their PHI. It is the responsibility of PIs to track the disclosures made in connection with their research protocols.

At the request of the covered entity, PIs must provide a complete list of all individuals whose PHI were disclosed under the HIPAA waiver, unless the covered entity determines that a simplified accounting is allowed by HIPAA. For disclosures of PHI for research purposes without the individual's authorization, and that involve at least 50 records, the Privacy Rule allows for a simplified accounting of such disclosures by ETSU. Under this simplified accounting provision, ETSU may provide individuals and/or covered entities with a list of all protocols for which the patient's PHI may have been disclosed, as well as the researcher's name and contact information.

The accounting must include disclosures of PHI with the following requirements:

i. Includes date of disclosure;
ii. Name and address of the person or entity to whom PHI was disclosed;
iii. Brief description of the PHI disclosed; and
iv. Brief statement of the purpose of the disclosures (in lieu of such a statement a copy of the written request for disclosure will suffice).

2) Limited Data Sets with a Data Use Agreement

A covered entity is permitted to use or disclose PHI included in a limited data set for research without individual authorization and without obtaining a waiver or alteration of authorization when the covered entity and the researcher enter into a data use agreement. Limited data sets may be used or disclosed only for purposes of research, public health, or health care operations. Because limited data sets may contain identifiable information, they are still PHI.

The limited data set must exclude all 18 HIPAA identifiers of the individual or of relatives, employers, or household member of the individual except for: addresses other than street name or street address or post office boxes; all elements of dates (such as admission and discharge dates); and unique codes or identifiers not listed as direct identifiers in section 164.514(e) of the Privacy Rule.

The Privacy Rule requires a data use agreement to contain the following provisions:

i. Specific permitted uses and disclosures of the limited data set by the recipient consistent with the purpose for which it was disclosed (a data use agreement cannot authorize the recipient to use or further disclose the information in a way that, if done by the covered entity, would violate the Privacy Rule);
ii. Identify who is permitted to use or receive the limited data set; and
iii. Stipulations that the recipient will

a. Not use or disclose the information other than permitted by the agreement or otherwise required by law;
b. Use appropriate safeguards to prevent the use or disclosure of the information, except as provided for in the agreement, and require the recipient to report to the covered entity any uses or disclosures in violation of the agreement of which the recipient becomes aware;
c. Hold any agent of the recipient (including subcontractors) to the standards, restrictions, and conditions stated in the data use agreement with respect to the information; and
d. Not identify the information or contact the individuals. Researchers who wish to use a limited data set must specify this in their IRB submission and clearly describe how the limited data set will be created. The IRB letter to the PI will specify that the research cannot begin until a Data Use Agreement is executed.

3) Preparatory to Research

A covered entity is permitted to use or disclose PHI for activities preparatory to research without individual authorization, without obtaining a waiver or alteration of authorization, and without a data use agreement. This provision might be used, for example, to allow a researcher to determine the feasibility of conducting a study.

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

1. 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;
2. That the researcher will not remove any PHI from the covered entity; and
3. That the PHI that the researcher seeks to use or access is necessary for the research purpose.

ETSU does not allow non-ETSU researchers to access PHI under the preparatory to research provision. Preparatory to research access is granted only to ETSU researchers. ETSU researchers who wish to access ETSU PHI under preparatory to research must have completed ETSU's HIPAA training within the last year. ETSU does not allow recording of identifiable information or use of information for recruitment of participants under preparatory to research.

For VA studies, activities preparatory to research refer only to activities that are necessary for the development of a specific protocol. The preparatory to research activity ends once the protocol has been submitted to the IRB for review. Preparatory to research access is granted only to VHA researchers. Non-VA researchers may not access VHA data for reviews preparatory to research.

4) Research on PHI of Decedents

A covered entity is permitted to use or disclose PHI of the deceased for research without authorization from the legally authorized representative or next of kin, without obtaining a waiver or alteration of authorization, and without a data use agreement.

In order for a covered entity to permit a researcher to access decedents' PHI, the covered entity must receive the following representation from the researcher:

i. The use and disclosure is sought solely for research on the PHI of decedents;
ii. The PHI for which use or disclosure is sought is necessary for the research purpose; and
iii. Documentation of the death of the individuals whose PHI is sought by the researchers.

VI. PHI has been de-identified according to the HIPAA requirements

A covered entity is permitted to use or disclose health information that is de-identified without restriction under the HIPAA Privacy Rule. Health information must be de-identified by removing certain pieces of information from each record or by statistical verification of de-identification.

Removal of 18 HIPAA Identifiers

The first way is by removing all 18 HIPAA identifiers of the individual, the individual's relatives, employers and household members. The covered entity also must have no actual knowledge that the remaining information could be used alone or in combination with other information to identify the individual who is the subject of the information. Under this method, the identifiers that must be removed are the following:

i. Names
ii. All geographic subdivisions smaller than a state (with limited exceptions)
iii. All elements of dates (except year) for dates directly related to an individual; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older.
iv. Telephone numbers
v. Fax numbers
vi. Electronic mail addresses
vii. Social Security numbers
viii. Medical record numbers
ix. Health plan beneficiary numbers
x. Account numbers

xi. Certificate/license numbers
xii. Vehicle identifiers and serial numbers, including license plate numbers
xiii. Device identifiers and serial numbers
xiv. Web universal resource locations (URLs)
xv. Internet protocol (IP) address numbers
xvi. Biometric identifiers, including finger and voice prints
xvii. Full face photographic images and any comparable images
xviii. Any other unique identifying number, characteristic, or code

Any code used to replace the identifiers is NOT allowed to be derived from any information related to the individual and the master codes, nor can the method to derive the code be disclosed. For example, the initials of a subject cannot be used to code data because the initials are derived from the name.

Statistical De-Identification
The second way is by a process of statistical de-identification. Instead of removing all 18 HIPAA identifiers, the covered entity must obtain verification from "a person with appropriate knowledge of and experience with generally accepted statistical and scientific principles and methods for rendering information not individually identifiable" that there is a "very small" risk that the information could be used by the researcher to identify the individual who is the subject of the information, alone or in combination with other reasonably available information. The person certifying statistical de-identification must document the methods used as well as the result of the analysis that justifies the determination. A covered entity is required to keep such certification, in written or electronic format, for at least 6 (six) years from the date of its creation or the date when it was last in effect, whichever is later.

VII. Consents and Waivers Obtained Prior to April 14, 2003

Researchers may use and disclose PHI that was created or received for research, either before or after the compliance date, if any one of the following was obtained prior to April 14, 2003:

1) An authorization or other express legal permission from an individual to use or disclose PHI for the research;
2) The informed consent of the individual to participate in the research; or
3) A waiver of authorization approved by either an IRB or a privacy board (in accordance with 45 CFR 164.512(i)(1)(i)); or a waiver of informed consent by an IRB in accordance with the Common Rule or an exception under FDA's human subject protection regulations at 21 CFR 50.24.

However, if a waiver of informed consent was obtained prior to April 14, 2003, but informed consent is subsequently sought after the April 14, 2003, an authorization

must be obtained (see section A for authorization requirements). If the subject is re-consented after April 14, 2003, a HIPAA authorization must be obtained.

VIII. Responsibilities

1) Researchers are responsible for:

1. Identifying any proposed access to, receipt of, use of, or disclosure of PHI which will occur during the research, and clearly specifying that in the IRB application, or on the form 129 (if requesting a determination of whether the activity involves human subject research).
2. Submitting a copy of their proposed HIPAA Authorization to the IRB. Researchers are responsible for ensuring that the authorization is consistent with the protocol and the informed consent; and that the authorization form covers the uses and disclosures necessary for the research.
3. Obtaining the valid, written authorization of each individual research participant.
4. Providing a copy of the *signed* authorization to each participant.
5. Non- VA researchers are responsible for retaining the signed authorizations for a period of no less than 6 (six) years from the end of the calendar year in which the research study was closed. VA researchers are required to maintain the signed HIPAA Authorization in accordance with VHA's Record Control Schedule 10-1 (RCS 10-1).
6. Researchers are responsible for ensuring that the uses or disclosures of PHI are limited to those described in the authorization, waiver, data use agreement, or other applicable agreements.
7. Researchers are responsible for tracking the disclosures made pursuant to a waiver of HIPAA authorization made in connection with their research protocols or made on PHI of decedents from whom authorization on behalf of the individual has not been obtained. Researchers are responsible for securely maintaining the record of disclosures for a period of no less than 6 (six) years from the end of the calendar year in which the research study was closed.
8. Researcher are responsible for ensuring PHI is created, used, disclosed, maintained and transmitted in compliance with the HIPAA rules and institutional policies relating to the same.
9. Researchers are responsible for reporting any breach or complaint related to PHI to the IRB and HIPAA Compliance Officer in a timely manner (refer to IRB Policy 18).
10. Researchers are responsible for contacting other institutions where their research will be conducted to ensure their knowledge of institution-specific policies regarding PHI.
11. Researchers are responsible for safeguarding research PHI by protecting the confidentiality and security of the PHI.
12. Researchers are responsible for ensuring that their HIPAA training is current.

2) The ETSU/VA IRB is responsible for:

1. Reviewing the HIPAA Authorization to ensure that all required elements are present, and that the authorization is consistent with the protocol and the informed consent
2. Determining that there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data before approving a study. In doing so, the IRB is responsible for taking into consideration the requirements of the Privacy Rule.
3. The IRB does not have the authority to approve stand-alone HIPAA Authorizations, and these documents will not be stamped with an IRB approval stamp.
4. Reviewing a request to waive or alter consent separately from reviewing a waiver of HIPAA authorization.
5. Reviewing, approving or denying, and documenting waivers of authorization under expedited or full-board review procedures, as appropriate.
6. Determining that the research meets all applicable criteria before the board approves a waiver or alteration of authorization under the Privacy Rule.
7. For non-VA studies, the ETSU/VA IRB is responsible for retaining documentation required by this policy for 6 (six) years from the date of the creation of the information, or the date when it was last was in effect, whichever is later. Records are maintained for 6 (six) years from the end of the calendar year in which the study is closed. For VA studies, the required records must be maintained in accordance with National Archives and Records Administration published in VHA's Record Control Schedule (RCS 10-1).

3) IRB Coordinator is responsible for:

1. Pre-reviewing all new submissions for the applicability of HIPAA, and assuring that a HIPAA Authorization or Waiver request is present, as applicable.
2. For non-VA studies, the ETSU/VA IRB Coordinator is responsible for pre-reviewing all HIPAA Authorizations to verify the presence of required elements in the HIPAA Authorization, both at initial submission and at the time of continuing reviews. For submissions that do not use the ETSU template, the ETSU/VA IRB Coordinator is responsible for obtaining review of the authorization from the ETSU HIPAA Compliance Officer. For VA research, the IRB Coordinator is responsible for verifying receipt of the separate HIPAA authorization that was reviewed and approved by the VA Privacy Officer.

4) ETSU HIPAA Compliance Officer is responsible for:

1. Serving as an advisor to the IRB regarding research use of PHI, evaluating research related complaints or allegations of non- compliance that involve PHI, and reporting issues or complaints related to PHI in research to the IRB.
2. Reviewing HIPAA Authorizations that do not use the ETSU template for initial studies.

3. Serving as an advisor to the IRB regarding security of research information, evaluating research related complaints or allegations of non-compliance that involve security of PHI or other sensitive data, and reporting issues or complaints related to data security in research to the IRB.

5) VA Privacy and Security Officer is responsible for, in relation to VA Studies:

1. Ensuring that the proposed research complies with all applicable local, VA, and other Federal requirements for privacy and confidentiality, and for information security, by identifying and addressing potential concerns about proposed research studies.
2. Reviewing the proposed study protocol, study specific privacy and security information, and any other relevant materials submitted with the IRB application.
3. Identifying deficiencies in the provisions for privacy and confidentiality or information security, respectively, of the proposed research, and making recommendations to the investigator and/or the IRB of options available to correct the deficiencies.
4. Following up with the investigator and/or the IRB, in a timely manner, to ensure the proposed research is in compliance with relevant privacy and confidentiality and information security requirements, respectively, before the investigator initiates the study.
5. Conducting a final review after the IRB has approved the study to ensure no further changes impact the privacy and security requirements of this study.

6) Vice Provost for Research (VPR) is responsible for:

1. Serving as a liaison to faculty and staff on research projects that involve PHI and for assuring that appropriate sanctions are imposed against researchers who do not comply with applicable policies regarding PHI.
2. Assuring that the IRB has written policies and implements those policies when reviewing studies that involve PHI.
3. Assuring that institutional agreements processed through Research and Sponsored Programs related to research comply with applicable policies.

7) Other responsibilities (non-VA entities):

1. Researchers are responsible for contacting the medical records or research departments of other covered entities to determine their policies.
2. MSHA/Ballad Health policies regarding use and disclosure of PHI are available upon request to the Ballad Health Research Department.
3. The ETSU/VA IRB is allowed under HIPAA rules to grant a waiver of authorization for research access and use to non-ETSU PHI. However, other institutions may choose to enforce additional requirements regarding the use and disclosure of their PHI.

IX. Compliance

Any allegations of non-compliance with HIPAA regulations in research received by the IRB will be reported to the ETSU HIPAA Compliance Officer as well as the VPR. If these non-compliance allegations involve a research study approved by the Veteran's Administration (VA), the VA Research Compliance and Privacy Officers will be informed, and appropriate institutional officials will also be notified (see Reporting Policy 34). ETSU's HIPAA Compliance Officer will investigate the allegations and, upon conclusion of the investigation, the IRB may defer to the ETSU HIPAA Compliance Officer regarding any remedial action or limitations regarding research involving the Investigator. Additionally, the IRB may take any action deemed appropriate for the protection of human subjects.

X. Retention of Records

HIPAA requires that the following records be securely kept for 6 (six) years after completion of the study. ETSU requires that all study records are retained for 6 (six) years from the end of the calendar year in which the study is closed. VA studies must follow the VA rules for record retention.

1) **IRB is responsible for retaining:**
   - Security and privacy policies and procedures, and template/forms implemented by the IRB to comply with HIPAA
   - All data use agreements submitted to the IRB
   - HIPAA waivers and associated research submissions
   - Any other documentation related to HIPAA and the IRB, including verification of HIPAA training for study staff and submitted expert de-identification verifications

2) **Researchers are responsible for retaining:**
   - All signed HIPAA authorizations, whether standalone or part of the informed consent
   - Accounting of disclosures
   - Copy of any signed Data Use Agreements for research with Limited Data Sets

3) **Vice Provost for Research is responsible for retaining:**
   - Copy of any signed Data Use Agreements for research with Limited Data Sets; also responsible for forwarding a copy of the Data Use Agreement to the IRB

Please note that if a research study creates protected health information during the course of the study that portion of the research generally becomes part of the patient's medical record and thus would need to be kept for the requisite 10 (ten) year period according to TN state law (or longer, if required by the covered component).

References:

45 CFR §164.501ETSU HIPAA Compliance Office:
https://www.etsu.edu/universitycounsel/hipaa/