WVU OHRP HIPAA Guidance

When Does HIPAA Apply?

WVU is a HIPAA Hybrid Entity. Per WVU Policy 1.11.3.6: The University is a single legal entity, comprised of multiple and distinguishable schools, departments, clinics, programs, and functions, some of which may conduct both covered functions and non-covered functions under HIPAA.

The University has determined that there are a number of its components that either do or do not use or disclose PHI; accordingly, to effectively and efficiently safeguard the use and disclosure of PHI and to focus its HIPAA compliance efforts on University Health Care Components, the University hereby elects to designate itself as a Hybrid Entity.

Exhibit A in the linked policy above outlines the departments, schools, clinics, programs, etc. in the covered entity.

Criteria for HIPAA Waiver

The following three criteria **must** be satisfied for a privacy board to approve a waiver of authorization under the Privacy Rule. At WVU, the WVU IRB serves as the HIPAA privacy board:

1. The use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements:
    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 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 the protected health information 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 protected health information would be permitted by this subpart;
2. The research could not practicably be conducted without the waiver; and
3. The research could not practicably be conducted without access to and use of protected health information.

Reminder: **Clinical access does NOT mean the electronic medical record (EMR) data can be accessed or used for research purposes. Using EMR data for research purposes requires reviews and approvals depending on the data, even if the researcher has access to the data for clinical employment purposes.**

When is a Wavier Appropriate?

1. identifying eligible potential participants for study through medical record review (Part of the project; recruitment; accessing the medical record prior to signed authorization)
2. secondary data analysis/research on a large set of medical records (Entire project)

A waiver for part of a project, or an entire project, can also be appropriate in other situations.

Research activities that involve PHI should be conducted whenever practicable **with patient authorization** (i.e., use of combined consent and authorization). If researchers have the opportunity to interact with the participant, researchers are expected to obtain a signed consent and HIPAA authorization. As noted above, study teams **must** demonstrate that the research could not practicably be conducted without the waiver. **This criterion is not met in situations where the study team will interact with the participant.** Likewise, it *may* be feasible to obtain a signed authorization from each individual in a small data set.

Additionally, researchers are reminded that informed consent and HIPAA authorization are *two separate activities*, governed by different regulations. The use of the combined consent and authorization allows the participant to sign once to both *consent* to the research and to provide *HIPAA authorization*. As such, a request for a waiver of informed consent or waiver of documentation of informed consent is separate from a request for a HIPAA waiver.

Data custodians (e.g., WVCTSI) may be able to provide a study team with a **de-identified** or a **coded dataset** that fulfills the research needs. De-identified datasets do not require a HIPAA Waiver but coded datasets may, depending on whether the researcher has access to the linking code.

General Guidance for Consent and HIPAA

The following guidelines are applicable for researchers in the covered entity **who are accessing (viewing and/or recording) participant PHI** or who will collect participant PHI during the course of a study.

*This guide is **not** comprehensive, nor does it represent each unique situation as it relates to human subjects research and HIPAA.*

Example	Consent Process	HIPAA	How/Required Forms
Secondary data analysis (retrospective chart review; no other research activities)	Waiver of informed consent	Waiver of HIPAA authorization	Request Waiver of Informed Consent in electronic submission system WVU OHRP-21 HIPAA Waiver of Authorization Request Form (WVU Build Form)
The study team will access/record EMR data prior to obtaining consent and authorization from the participants. Project includes retrospective chart review and	May request waiver of informed consent depending on specifics of retrospective component. Signed informed consent **with** access to medical record/PHI prior to signature	Waiver of HIPAA authorization (for access to medical record/PHI prior to participant signature) Signed HIPAA authorization	Request Waiver of Informed Consent in electronic submission system, if applicable WVU OHRP-21 HIPAA Waiver of Authorization Request Form (WVU Build Form)

prospective component.			WVU OHRP-24 Adult Medical Consent Template (combined consent and authorization)
Prospective study (all activities)	Signed informed consent **without** access to medical record/PHI prior to signature	Signed HIPAA authorization	WVU OHRP-24 Adult Medical Consent Template (combined consent and authorization)
Projects that include a survey/interview as well as a chart review	Waiver of documentation of informed consent (no signature)* and will access EMR	Signed HIPAA authorization *or* HIPAA Waiver	WVU OHRP-25 Informational Cover Letter - Exempt, Flex, NHSR *or* WVU OHRP-27 Expedited Cover Letter Template WVU OHRP-21 HIPAA Waiver of Authorization Request Form (WVU Build Form) *or* WVU OHRP-38 Standalone HIPAA Authorization Form

*If utilizing the same participant population for both the survey/interview/activity with waiver of documentation and chart review, study is unlikely to meet criteria for HIPAA waiver.
**Please email irb@mail.wvu.edu if have a research project not covered by the situations outlined above/if you have questions or concerns

Request HIPAA Waiver

To request a HIPAA waiver, please visit https://human.research.wvu.edu/forms#hipaa and select WVU OHRP-21 HIPAA Waiver of Authorization Request Form (WVU Build Form). The approved HIPAA waiver must be attached to the electronic protocol submission and the information included in the HIPAA waiver **must be congruent** with the information provided in the protocol and the Data Protection Certificate. Discrepancies may result in revisions to request changes in the protocol, data protection form, and/or resubmission/modification of the HIPAA waiver request.

References

- WVU OHRP SOP 036: Research Data Protection and HIPAA
- HIPAA Hybrid Entity Designation Policy
- WVCTSI

- 45 CFR 164.512(i)(1)(i) and 45 CFR 164.512(i)(2)
- Office of Civil Rights main HIPAA site
    - Research and HIPAA Privacy Rule page. Heading: "Documented Institutional Review Board (IRB) or Privacy Board Approval."
- HIPAA Privacy Rule Information for Researchers from NIH
    - Waiver or Alteration of the Authorization Requirement