

IRBNews



Office for the Protection of Human Research Subjects

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HIPAA Alteration/Waiver

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 a waiver or alteration 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.

In addition, 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.

Once this request is received, 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." 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.

Researcher Responsibilities:

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



EAST TENNESSEE STATE
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