

Below are required elements for an Authorization under HIPAA to be approved for this application.

Mark the box by the elements **NOT COMPLETED** and which still need to be addressed by the researcher (if you determine all elements are included, no boxes should be check marked).

- The name of the researcher(s) authorized to make the use or disclosure of the PHI.
- A description that identifies PHI to be used/disclosed in a specific and meaningful fashion.
- An explanation that information disclosed pursuant to the authorization may no longer be protected when re-disclosed by the recipient.
- A statement that a subject's treatment, payment or enrollment in any health plan or their eligibility for benefits will NOT be affected if they refused to sign the authorization.
- A statement that the subject may not participate in a research study if they refuse to sign the authorization.
- A description of how the individual may revoke the authorization in writing and the exceptions to the revocation (researcher may use data already collected, PHI may be used/disclosed if adverse event occurs, subject may not be able to participate in the study);
- An expiration date or an expiration event that relates to the use or disclosure ("end of the research study," "none," or similar language is sufficient if the authorization is research).
- A space for signature of the individual and date. If a personal representative signs the authorization, a description of the representative's authority must be provided.
- The authorization written in plain language AND the statement that the subject will be given a copy of the signed authorization.
- Optional statement that review of PHI is not permitted by the subject until the study is completed.

IRB Decision:

- The authorization form is APPROVED by the IRB based on the information related to the IRB by the researcher in this application.
- The authorization form is NOT APPROVED by the IRB based on the information related to the IRB by the researcher in this application.

Comments about elements and/or explanation for not approving: