

University of Kentucky
HIPAA Authorization Form Checklist

Primary Reviewer: _____ IRB #: _____ PI: _____

Title of
Project:

Dear IRB member,

This is a guide to help you (the reviewing IRB member) ensure that all of the elements required for an authorization under HIPAA are included in this application.

Please check the appropriate box(es) of elements that are completed in the authorization application as you are reviewing the application. Attached is the template authorization that the investigators were given to use as a guide. We suggest that if you are not sure if a statement qualifies for a certain category, use the comments feature of your Adobe Acrobat program to put a [?] beside that box and a few comments to explain what the issue is.

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.

A description of each research project and reason to share the requested use or disclosure.

The name of the person(s)/entity(ies) with whom the researcher may use or disclose the PHI.

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.

Explanation:

Review Date