

HIPAA Authorization Regulations

According to HIPAA requirements outlined in 45 CFR 164.508, researchers should obtain written authorization from subjects before using or collecting protected health information (PHI) whenever possible. Authorization should be obtained in writing from prospective subjects.

Under HIPAA, the following core elements and statements must be included in the authorization document. Attached is a template authorization form for your guidance.

- A description that identifies the individually identifiable protected health information to be used/disclosed in a specific and meaningful fashion (e.g., list the types of data to be collected from the medical record);
- The name of the person(s) or class of persons to whom the covered entity may make the requested use or disclosure (i.e., researchers must list all of the entities that might have access to the study's PHI such as ORI/IRB, University of Kentucky/Hospital representatives, sponsors, Food and Drug Administration, data safety and monitoring board or any others given authority by law);
- A description for each purpose of the requested use or disclosure (e.g., list reasons why the PHI is collected such as to be able to conduct the research and to ensure that the research meets legal, institutional, or accreditation requirements; list purpose of research);
- An expiration date or an expiration event that relates to the use or disclosure (i.e., length of time researchers plan to maintain the data). The statement "end of research study", "none", or similar language is sufficient;
- A description of how the individual may revoke the authorization and the exceptions to the revocation; or a copy of the Privacy Notice which explains how to revoke the authorization and the exceptions to the revocation (i.e., HIPAA gives subjects the legal right to revoke authorization. The subjects must be told how they can withdraw. Any request for revocation must be in writing. Also, the subjects should be told that if they do revoke, that they can no longer participate in research and that researchers may use the PHI already obtained to maintain the integrity of the data.);
- A statement that a subject's treatment, payment or enrollment in any health plan or their eligibility for benefits will not be effected if they refuse to sign the authorization;
- A statement that the subject may not participate in a research study if they refuse to sign the authorization;
- An explanation that information disclosed pursuant to the authorization may no longer be protected when re-disclosed by the recipient (i.e., if the researchers disclose the information collected to a third party then the HIPAA protections may no longer be in place);

- A signature of the individual and date. If a personal representative signs the authorization, a description of the representative's authority must be provided;
- Optional item: Under HIPAA, subjects have the right to access their PHI. In research, this right can be suspended while the research is in progress. However, subjects must be told in the authorization that this right has been suspended and the conditions of the suspension must be listed. The subjects should also be informed that their right to access the PHI will be reinstated at the conclusion of the research study.
- The authorization must be written in plain language;
- The subject must be given a copy of the **signed** authorization.

Attached is a template authorization form for your guidance. An electronic copy of the template can be obtained by contacting Crystal May at cdmay1@email.uky.edu or (859) 257-9428 or go to <http://www.research.uky.edu/ori/HIPAA/main%20page.htm#HIPAAForms>.

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