



Additional Requirements for Informed Consent Documents Under HIPAA

Note: the following is a list of requirements for a proper authorization under the Health Insurance Portability and Accountability Act of 1996 and related privacy regulations (“HIPAA”). They are in addition to and not instead of the requirements of the Common Rule for informed consent. For more on Common Rule requirements, see 45 C.F.R. §§ 46.116 and 46.117 or visit the following site: <http://ohrp.osophs.dhhs.gov/humansubjects/assurance/consentckls.htm>.

Required Elements:

The following information must be included in a HIPAA-compliant authorization document:

- A description of the information to be used or disclosed in connection with the research project that identifies the information in a specific and meaningful fashion (e.g., “your complete medical record” or “information related to treatment of your cancer”).
- The name or other specific description of the person, or class of persons, authorized to make the requested use or disclosure (e.g., “Professor Jones” or “the University of Michigan” or “health care providers involved in your heart failure treatment”).
- The name or other specific description of the person, or class of persons, to whom the requested uses or disclosures may be made (e.g., “the researchers” or “individuals responsible for oversight of the research project” or “Professor Jones at the Cleveland Clinic”).
- A description of each purpose of the requested use or disclosure (e.g., “to help us monitor your response to Drug X”).
- An expiration date or an expiration event that relates to the individual or the purpose of the use or disclosure. The statement “end of the research study,” “none,” or similar language is generally acceptable for research projects, including research databases.
- Signature of the patient/potential subject and date. If the authorization is signed by a personal representative of the patient, also include a description of the representative’s authority to sign (e.g., spouse, power of attorney, etc.).

Required Statements:

In addition to the elements listed above, statements notifying a patient/potential subject of the following must also be included:

- The patient’s right to revoke the authorization in writing and either: (i) the exceptions to the right to revoke and a description of how to revoke; or (ii) a reference to the Notice of Privacy Practices if the information concerning revocation, if this is consistent with revocation rights related to participation in the research project.
- Notification of the consequences of the individual’s refusal to sign the authorization (e.g., no enrollment in the research project).
- Any information disclosed pursuant to the patient's authorization may be subject to redisclosure by the recipient and no longer protected by the Health Insurance Portability and Accountability Act of 1996.

A copy of the signed authorization must be provided to the subject.

IMPORTANT: An authorization is considered defective if the expiration date has passed, if the authorization has been revoked by the patient, or if any of the elements or required statements listed above is missing.