

45 CFR 164.508 (Privacy Rule) Requirements

Research Authorizations for Use or Disclosure of Protected Health Information

Definitions:

Protected Health Information (PHI) means individually identifiable health information that is transmitted or maintained by DSHS (or by any other covered entity) in any form or medium.

Treatment means the provision, coordination, or management of health care and related services by one or more health care providers.

Required Elements:

1. A specific and meaningful description of the information to be used or disclosed;
2. The name or other specific identification of the person(s), or class of persons, who are authorized to make the requested use or disclosure;
3. The name or other specific identification of the person(s), or class of persons, who will receive the information;
4. A description of each purpose of the requested use or disclosure.
5. A statement of the ability or inability to condition treatment, payment, enrollment or eligibility for benefits on the authorization as follows:
 - (a) A covered health care provider may condition the provision of **research-related treatment** on provision of an authorization for use or disclosure of protected health information for such research. In this case the consequences to the individual of a refusal to sign the authorization must be described.
 - (b) A covered entity may not condition the provision of non-research related treatment, or payment, enrollment or eligibility for benefits on whether the individual signs the authorization for research disclosure of protected health information.
6. A statement explaining the extent to which the information disclosed under the authorization is subject to redisclosure by the party that receives the information.
7. A statement that the individual may revoke the authorization in writing, a description of the exceptions to the right to revoke (i.e., the extent to which action has already been taken on the authorization before it is revoked), a description of how the individual may revoke the authorization, and a reference to the covered entity's privacy notice if information disclosed is included in the privacy notice.

8. An expiration date or expiration event that relates to the individual or the purpose of the use or disclosure. (For research, it is sufficient to state "end of the research study," "none," or other similar language.)
9. The signature of the individual and the date.

Other Requirements:

An authorization for the use of PHI for research may be combined with any other type of written permission for the same research study, including another authorization for the use or disclosure of PHI for such research or a consent to participate in such research.

The authorization must be written in plain language. A copy of the signed authorization must be provided to the individual.