

An Authorization for the Use or Disclosure of Protected Health Information for Research must include certain core elements and certain Required Statements, as follows:

### Core Elements

1. A description of the PHI to be used or disclosed, identifying the information in a specific and meaningful manner.
2. The names or other specific identification of the person or persons (or class of persons) authorized to make the requested use or disclosure.
3. The names or other specific identification of the person or persons (or class of persons) to whom the covered entity may make the requested use or disclosure.
4. A description of each purpose of the requested use or disclosure.
5. Authorization expiration date or expiration event that relates to the individual or to the purpose of the use or disclosure (“end of the research study” or “none” are permissible for research).
6. Signature of the individual and date. If the individual’s legally authorized representative signs the authorization, a description of the representative’s authority to act for the individual must also be provided.

### Required Statements

1. A statement of the individual’s right to revoke his/her authorization and how to do so, and, an explanation of any exceptions to the right to revoke.
2. Whether treatment, payment, enrollment, or eligibility of benefits can be conditioned on the authorization, including research-related treatment and consequences of refusing to sign the authorization.
3. A statement of the potential risk that PHI will be re-disclosed by the recipient. This may be a general statement that the Privacy Rule may no longer protect health information disclosed to the recipient.

### Sample Authorization

Researchers are advised to adapt the following sample authorization [the bracketed material identifies the core elements and required statements and provides examples, do not include brackets in the actual authorization]:

## “Authorization to Use or Disclose Protected Health Information for Research”

Signing this informed consent to participate in the research study that it describes, also authorizes [Core Element #2, Examples: “Dr. Smith’s Office”, or “Millcreek Community Hospital”, or “any doctors or hospitals that have treated your cancer”, etc.] to disclose [Core Element #1, Examples: “blood test results”, “your diagnosis and all medical records associated with your hospital stay”, “your entire medical record”, etc.] to [Core Element #3, Examples “the Investigator, Dr. Jones” or “the research team” or “Dr. Jones and his research assistants”, etc.] in order to [Core Element #4] permit this information to be used in the research study. This authorization will expire [Core Element #5, Examples: “at the conclusion of the research study”, “after the one-time disclosure of the information”, “after the five-year follow-up period has ended”, “on May 22, 2056”, etc.].

[Required Statement #1] This authorization may be revoked at any time by contacting the Investigator at [include address], but that the revocation will not affect any information that may already have been used or disclosed before then.

[Include Required Statement #2, Examples: “If you do not authorize the use or disclosure of your health information, you will be unable to participate in this research study and thus will not be able to receive the experimental treatment, but it will have no other affect on your ability to receive the standard treatment or on any other payment, enrollment, or eligibility for any other benefits” or, “Not authorizing the use or disclosure of your health information will have no affect on your treatment, payment, enrollment, or eligility of benefits,” etc.]

[Required Statement #3] The Federal Privacy Rule may no longer protect the health information that is disclosed to the recipient if the recipient is not itself covered by the Rule.”