# Determine Whether Your Practice Uses and Discloses PHI for Research Purposes

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Practice Name

Practices may use a patient’s PHI for research purposes under the following conditions: (1) the practice obtains signed authorization from the patient; (2) an Institutional Review Board (IRB) or Privacy Board grants a waiver of authorization for the research; or (3) the Practice limits the disclosure of PHI to conform with the Limited Data Set rules and obtains Data Use Agreements, as necessary.

**Research Authorizations**

If the Practice does not qualify or obtain a research authorization waiver from an IRB or Privacy Board, the Practice must obtain an authorization from the patient prior to using or disclosing his/her PHI for research purposes.

See Step 8 for the list of required elements to all authorizations. Please note that “none” may be used as the expiration date/event on the authorization, as long as it includes a corresponding statement that the authorization will have no expiration date or event. As with other authorizations, the research authorization must clearly indicate that the patient may revoke the authorization and must provide the procedure for doing the same. If an individual revokes his/her authorization for research, the PHI used or disclosed prior to such revocation may continue to be used to the extent necessary to preserve the integrity of the research study. However, after such revocation, the practice may not continue to use or disclose additional PHI.

Exhibit 6 may be used to obtain authorization from the patient to use and disclose PHI for research purposes.

If the research also involves the provision of research-related treatment to the individual and the individual refuses to sign an authorization for the research, than the practice may withhold such research-related treatment.

**Research Waiver**

In lieu of a patient authorization, PHI may be used or disclosed for research purposes in limited instances based upon IRB or Privacy Board determinations that PHI will remain protected and that the research project depends upon such PHI. The IRB or Privacy Board may waive all or part of the requirement to obtain a patient authorization, if the following criteria are satisfied:

◆ the use or disclosure of PHI involves no more than minimal risk to the privacy of the individual, based on at least the following:

 • a plan to protect the PHI from improper use and disclosure;

 • a plan to destroy the PHI at the earliest opportunity unless retention of the PHI is required by law; and

 • a written assurance that the PHI will not be used or disclosed to a third party except as required by law or permitted by an authorization.

◆ the research cannot be conducted without a waiver of authorization; and

◆ the research cannot be conducted without access to the patient’s PHI.

**Current/Ongoing Research Protocols**

If the practice is currently using or disclosing PHI in accordance with existing research protocols, the practice may continue to do so provided that the practice has received one of the following unrestricted permissions:

◆ written authorization or other express legal permission from an individual to use or disclose PHI for the research;

◆ the informed consent of the individual to participate in the research; or

◆ a waiver by an IRB of the informed consent, in accordance with applicable law, so long as informed consent is not subsequently sought from individuals participating in the research.

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| **Note:**• Treatment of a patient may be conditioned on completion of the authorization form if the treatment is being provided solely for the purposes of research. If not, then the practice cannot condition treatment based on receiving a signed authorization form.• Once the authorization is signed, the practice is required to provide a copy of the signed authorization to the patient. In addition, the practice must retain a record of the authorization for six (6) years at a minimum.continued• If the practice will receive any payment from a third party for using and disclosing the patient’s PHI for research purposes, then the authorization form must include a statement to that effect.• Since IRBs and Privacy Boards may have difficulty in interpreting data sent by practices and because their review may be purely objective, HHS intends to issue further guidance to address these concerns. |

**Limited Data Set**

If the Practice intends to use or disclose patient PHI for the creation of a Limited Data Set to be used for research purposes, then the Practice should enter into Data Use Agreement(s) (and/or Business Associate Agreements, with appropriate language included regarding Limited Data Set use) with the recipients of the Limited Data Set, as described in Appendix 8.