

**SHEPPARD AND ENOCH PRATT FOUNDATION**  
***PRIVACY MANUAL***

Directive No. PM-340  
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Effective: October 1, 2004

SUBJECT: Use and Disclosure of Protected Health Information for Research

APPROVED: \_\_\_\_\_  
President & Chief Executive Officer

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Executive Vice President & Chief Operating officer

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**PURPOSE:**

Protected health information (PHI) that is obtained in the course of providing care may sometimes be used in research activities. This policy outlines the permitted uses and *disclosures* of PHI for research purposes and provides detailed policy to support the SHEPPARD PRATT Institutional Review Board (IRB) Policies and Procedures pertaining to the use of PHI.

The following research is not subject to this policy:

- De-identified records review (See DE-IDENTIFIED INFORMATION POLICY)
- Research that does not involve PHI
- Anonymous surveys

**Definition(s):**

**PHI** (protected health information) is individually identified health information in any form or medium.

**Research** is defined as “a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.” Any project involving PHI where one of the primary goals is generalizable knowledge, with or without publication or public presentation, is considered research.

**POLICY:**

1. As a general rule, a researcher must obtain an Authorization from all participants in research prior to the internal use or external disclosure of PHI for any research related purpose that is not otherwise permitted or required under this policy. PHI may be used or disclosed for purposes of research in accordance with the provisions of a written *authorization* that complies with the requirements of SHEPPARD PRATT policy: **AUTHORIZATIONS TO USE OR DISCLOSE PROTECTED HEALTH INFORMATION**. Patient names will not be provided to a researcher without written authorization from the patient for such information to be provided.

2. If the Institutional Review Board (IRB) has approved a modification of the authorization in accordance with this policy, PHI may be used or disclosed for purposes of research in accordance with the provisions of a written authorization that does not comply with the requirements of SHEPPARD PRATT policy AUTHORIZATIONS TO USE OR DISCLOSE PROTECTED HEALTH INFORMATION. The authorization must comply with all terms required by the IRB and with this policy.
  - 1.1. **Checklist to Validate Authorization Forms:** Unless expressly waived by the IRB, an authorization to use or disclose protected health information (PHI) for research must contain the following elements:
    - A description of the information to be used or disclosed.** Description should be specific and documented in a meaningful fashion.
    - The name or other specific identification of who is authorized to use or disclose the information.** Examples: “Sheppard Pratt” or “Dr. XXX.”
    - The name or other specific identification of the person or organization to which Sheppard Pratt is authorized to make the disclosure.**
    - A description of each purpose of the requested use or disclosure.**
    - An expiration date, or an expiration event that relates to the patient or to the reason for the use or disclosure.** The statement “end of the research study” or “none” is sufficient if the authorization is for a use or disclosure of PHI for research, including for the creation and maintenance of a research database or research repository.
    - A statement that the patient has the right to revoke the authorization in writing, and that the revocation does not apply:**
      - To the extent that action has been taken in reliance on the authorization; and;
      - If the authorization is to permit disclosure of PHI to obtain payment or coverage, to the extent that other law allows the payor to contest claims or coverage.
    - A description of how the patient may revoke the authorization.**
    - A statement that the patient does not have to sign the authorization as a condition of receiving treatment from Sheppard Pratt, except:**
      - If the treatment is research-related, provision of treatment may be conditioned on receipt of an authorization to use and disclose PHI related to this treatment as necessary for the research; or
      - If the purpose of the treatment services is to create PHI for disclosure to a third party, provision of the services may be conditioned on receipt of an authorization to disclose the PHI to that third party.
    - A statement that information that is disclosed in accordance with the authorization may be disclosed further by the recipient, and that the information may no longer be protected by federal privacy rules regarding protected health information.**

- ❑ **The patient's signature, or the signature of the patient's personal representative, with a description of the representative's authority to act for the patient.** Example: "power of attorney."
- ❑ **The date of the signature.**

1.2. An authorization for research that **includes treatment** may:

1.15.1. Be combined with consent to participate in the research, or with any other legal permission related to the research study.

1.15.2. Condition the provision of treatment in the research study on obtaining an authorization to use and disclose PHI (45 CFR 164.508)

3. PHI may be used or disclosed for purposes of research without authorization, if the IRB has approved a waiver of authorization that applies to PHI that is obtained in connection with a specified research study. The waiver must comply with this policy.

### **Accounting for Research Disclosures**

4. HIPAA Privacy Regulation 164.528 "Accounting of Disclosures of Protected Health Information requires the accounting of when and to whom SHEPPARD PRATT discloses PHI that is not for treatment, payment or health care operations (refer to Accounting of Disclosure Policy) and for which a properly executed authorization from the patient has not been obtained.

Among the types of disclosure **exempt** from this accounting requirement are:

- 1.1. Research disclosures made pursuant to an individual's authorization
- 1.2. Disclosures of the limited data set to researchers with a data use agreement
- 1.3. A simplified accounting provision is defined in 45 CFR 164.512(i) for a particular research purpose that involves at least 50 records. The simplified accounting provision must include:
  - 1.2.1. The name of the protocol or other research activity;
  - 1.2.2. A description, in plain language, of the research protocol or other research activity, including the purpose of the research and the criteria for selecting particular records;
  - 1.2.3. A brief description of the type of PHI that was disclosed;
  - 1.2.4. The date or period of time during which such disclosures occurred, or may have occurred, including the date of the last such disclosure during the accounting period;
  - 1.2.5. The name, address, and telephone number of the entity that sponsored the research and of the researcher to whom the information was disclosed; and

- 1.2.6. A statement that the PHI of the individual may or may not have been disclosed for a particular protocol or other research activity.
- 1.2.7. If an individual receives an accounting that uses this research option, and if it is reasonably likely that the PHI of the individual was disclosed for the research protocol or activity, SHEPPARD PRATT will assist the individual in contacting the entity that sponsored the research and the researcher, if so requested

### **Access of Individuals to PHI (45 CFR 164.524)**

1. As a general rule, individuals who participate in research have a right to access their own PHI that is maintained in a “designated record set”. Designated record sets are those that are used to make treatment, payment and healthcare operations decisions about individuals. Research data sets are not considered to be included in the “designated record sets” unless the data about an individual that is generated in clinical research is entered into the individual’s medical or financial records which are normally part of the designated record set.
6. Individuals participating in research protocols that include treatment may be temporarily denied access to their PHI obtained in connection with that research protocol, **provided that**:
  - 6.1. The PHI was obtained in the course of the research;
  - 6.2. The individual agreed to the denial of access in the Research Authorization;
  - 6.3. The research remains in process; and
  - 6.4. The individual’s rights to access such PHI are re-instated once the research study has concluded.

### **Institutional Review Board Waiver**

7. **Partial Waiver of Authorization Solely for the Purpose of Identifying, Prescreening, Contacting and/or Recruiting Potential Research Participants.** Since a researcher cannot practicably obtain potential research participant’s authorization for review of PHI in advance of contacting the potential participant, the IRB may issue a limited waiver of authorization permitting specified access and use of PHI solely for identifying, prescreening and recruitment contact pursuant to an approved protocol.
  - 7.1. Physicians and other health care professionals who are employees or independent contractors of Sheppard Pratt and have a direct treatment relationship with an individual may review that individual’s PHI for eligibility with respect to a research protocol and may initiate a discussion with the individual about potential participation as a research subject in a protocol relevant to the treatment relationship. This scenario does not require an Authorization or Waiver of Authorization if the IRB obtains from the researcher representations that:

- 7.1.1. Use or disclosure is sought solely to review PHI as necessary to prepare a research protocol, to identify possible subjects, or for similar purposes preparatory to research;
    - 7.1.2. No PHI is to be removed from Sheppard Pratt by the researcher in the course of the review; and
    - 7.1.3. The PHI for which use or access is requested is necessary for the research.
  - 1.1 Partial authorization waivers may **be granted** to researchers who are not employees or independent contractors of Sheppard Pratt for purposes of identifying potential research subjects and obtaining PHI necessary to recruit potential research subjects if the IRB obtains from the researcher representations that:
    - 1.1.1 Use or disclosure is sought solely to review PHI as necessary to prepare a research protocol, to identify possible subjects, or for similar purposes preparatory to research;
    - 1.1.2 The PHI for which the waiver is sought is necessary for research purposes.
  - 1.2 Partial authorization waivers granted pursuant to Section 7.2 shall be documented by the IRB as provided in Section 9 below.
- 2 **Research on Decedents’(deceased patients):** Research access to PHI of deceased individuals does not require an authorization or waiver of authorization if the IRB obtains from the researcher representation of the following:
  - 2.1 The use and disclosure is sought solely for research on the PHI of decedents
  - 2.2 PHI for which use or disclosure is sought is necessary for the research purposes, and
  - 2.3 Documentation, at the request of the IRB of the death of the individuals whose PHI is sought by the researchers.
- 3 **Waiver of Authorization or Partial Waiver of Authorization by IRB for research access, use or disclosure of PHI.** The Sheppard Pratt IRB may grant a waiver, in whole or in part, from the requirements of the usual informed authorization for research use of PHI, provided all of the following criteria are satisfied and documented:
  - 3.1 Identification of the IRB and the date on which the alteration or waiver of authorization was approved;
  - 3.2 A statement that the IRB has determined that the alteration or waiver of authorization, in whole or in part, satisfies the **three criteria** set forth by the HIPAA Privacy Regulation, including:
    - 3.2.1 A statement that the proposed uses and disclosures of information involve no more than minimal risk to the individual. (“Risk” in this context applies to the consequences of using or disclosing the PHI in connection

with the study, and does not relate to any clinical or medical risk to research subjects that may result from the research itself): based on the following:

- 3.2.1.1 There is an adequate plan to protect the identifiers from improper use and disclosure;
  - 3.2.1.2 There is an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and
  - 3.2.1.3 There are adequate written assurances that the PHI will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of PHI would be permitted by this subpart;
  - 3.2.2 A statement that the research could not practicably be conducted without the waiver.
  - 3.2.3 A statement that the research could not practicably be conducted without access to and use of the PHI.
  - 3.3 A brief description of the PHI that is necessary for the research.
  - 3.4 A statement that the waiver has been approved under either normal or expedited procedures of the Common Rule governing the IRB.
  - 3.5 Signature of the chair, or other designated member, of the IRB.
1. Uses or disclosures of PHI made pursuant to a Waiver are subject to the Minimum Necessary rules requiring that the PHI used or disclosed be only “the information reasonably necessary” to accomplish the purpose for which the use or disclosure of PHI is sought or requested..
  2. Instead of a partial waiver of authorization, the IRB may choose to alter the form of the authorization from the standard form as provided for in SHEPPARD PRATT policy AUTHORIZATIONS TO USE OR DISCLOSE PROTECTED HEALTH INFORMATION. An approved alteration of the authorization form must be documented in conformance to the above requirements.
  3. Individuals responding to an advertisement or otherwise initiating contact and indicating interest in participating in research study may be given an explanation of the study (including, but not limited to, the name of the principal investigator and description of the study) without Authorization or Waiver of Authorization. However, either their authorization or a waiver of authorization is required to review PHI in their health care records to determine potential eligibility.

**Documentation**

11. All documentation related to approved waivers and alterations of authorizations for PHI that is used or disclosed in connection with a research study must be retained for at least six years after the date that the study was completed by the IRB.
12. Anyone desiring to use or disclose PHI that is in the custody of SHEPPARD PRATT for purposes of research must either obtain written authorization for such use or disclosure from each individual to whom the PHI pertains (in accordance with SHEPPARD PRATT AUTHORIZATION TO USE OR DISCLOSE PROTECTED HEALTH INFORMATION policy), or must obtain a waiver of authorization or approved alteration of authorization from the IRB in accordance with this policy.

**REFERENCE:** 45 CFR § 164.512(i)

See also: ACCOUNTING OF DISCLOSURES OF PROTECTED HEALTH INFORMATION  
SHEPPARD PRATT INSTITUTIONAL REVIEW BOARD POLICY AND  
PROCEDURE  
MINIMUM NECESSARY

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4/14/2004