Policy and Procedure: *HIPAA/HITECH Compliance*
Topic: *Research*

HIPAA Regulation:

- *Research* §164.501, 164.508, 164.512(i) (See also 164.514(e), 164.528, 164.532)

Policy Purpose:

The purpose of this policy is to describe practices related to the use and disclosure of Protected Health Information for the purpose of research in accordance with the HIPAA requirements.

Policy Description:

It is the policy of **Saratoga Bridges** to comply with the Health Information Portability and Accountability Act (HIPAA), the Health Information Technology for Economic and Clinical Health Act (HITECH), the Common Rule (45 CFR 46.107), and Food and Drug Administration (FDA) Protection of Human Subjects Regulations (21 CFR Parts 50 and 56) requirements related to research and the use and disclosure of protected health information (PHI) and individually identifiable health information.

Research is defined in the Privacy Rule as "a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge."

Policy Responsibilities:

Privacy Officer

1. Determines whether or not the use or disclosure for research purposes requires an authorization by the individual or the individual's personal representative. **An authorization must be obtained unless one of the following exceptions is met:**
    a. The research study uses only PHI of deceased individuals.
    b. The information is released in the form of a limited data set, with certain identifiers removed and with a data use agreement between the researcher and **Saratoga Bridges**; a "data use agreement" must be obtained from all recipients of the limited data set.
    c. The researcher uses only "de-identified" PHI in conducting the research study; in which case, the health information is no longer PHI.[i]

   d. The information is preparatory to research. Representation must be obtained from the researcher, either in writing or orally, that the use or disclosure of the protected health information is solely to prepare a research protocol or for similar purposes preparatory to research, that the researcher will not remove any protected health information from the Saratoga Bridges, *and* representation that protected health information for which access is sought is necessary for the research purpose. This provision might be used, for example, to design a research study or to assess the feasibility of conducting a study.
   e. A waiver of authorization has been approved by the Research Review Board. There must be written documentation that an alteration or waiver of the research participants' authorization for use/disclosure of information about them for research purposes has been approved by the Research Review Board.[ii]
   f. There must be written documentation that an alteration or waiver of the research participants' authorization for use/disclosure of information about them for research purposes has been approved by the Research Review Board.[iii]
2. Reviews the Authorization for the Use or Disclosure of Protected Health Information form to assure the authorization for research is valid. To be valid, an authorization must include:
   a. A description of the individually identifiable health information to be used in the research study.
   b. A list of all persons (or titles of persons) who may use or disclose the individually identifiable health information.
   c. **Saratoga Bridges** specifically named as authorized to disclose the information.
   d. A list of the persons (or titles of persons) specifically authorized to receive the information.
   e. A description of the purpose for which the information will be disclosed.[iv]
   f. An expiration date or expiration event; for research purposes, this statement can be "end of the research" or "none".
   g. Dated signature of the research participant or legally authorized representative (if signed by a representative, a description of the representative's authority to act for the individual should be included).
   h. A statement of the research participant's right to revoke the authorization.
   i. A statement that information disclosed pursuant to the authorization may be further re-disclosed and no longer protected by HIPAA.
   j. If the research is not treatment related, a statement that the research participant has the right to refuse.
   k. If the research does not involve research-related treatment, a statement that the research subject will not be denied treatment for refusal to sign the authorization.
3. Provides a copy of the signed authorization to the individual or legally authorized representative.
4. Files the signed authorization in the HIPAA section of the record.

END NOTES:

[i] De-identified health information-neither identifies nor provides a reasonable basis to identify an individual. There are two ways to de-identify information; either: 1) a formal determination by a qualified statistician; or 2) the removal of specified identifiers of the individual and of the individual's relatives, household members, and employers is required, and is adequate only if the covered entity has no actual knowledge that the remaining information could be used to identify the individual.

The following is a listing of the eighteen (18) identifiers:

(A) Names
(B) All geographic subdivisions smaller than a state, including street address, city, county, precinct, ZIP code, and their equivalent geocodes, except for the initial three digits of the ZIP code if, according to the current publicly available data from the Bureau of the Census:
    (1) The geographic unit formed by combining all ZIP codes with the same three initial digits contains more than 20,000 people; and
    (2) The initial three digits of a ZIP code for all such geographic units containing 20,000 or fewer people is changed to 000
(C) All elements of dates (except year) for dates that are directly related to an individual, including birth date, admission date, discharge date, death date, and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older
(D) Telephone numbers
(E) Fax numbers
(F) Email addresses
(G) Social security numbers
(H) Medical record numbers
(I) Health plan beneficiary numbers
(J) Account numbers
(K) Certificate/license numbers
(L) Vehicle identifiers and serial numbers, including license plate numbers
(M) Device identifiers and serial numbers
(N) Web Universal Resource Locators (URLs)
(O) Internet Protocol (IP) addresses
(P) Biometric identifiers, including finger and voice prints
(Q) Full-face photographs and any comparable images
(R) Any other unique identifying number, characteristic, or code, except for re-identification codes

[ii] A covered entity may use or disclose protected health information for research purposes pursuant to a waiver of authorization by an IRB or Privacy Board, provided it has obtained documentation of *all* of the following:

- Identification of the IRB or Privacy Board and the date on which the alteration or waiver of authorization was approved;
- A statement that the IRB or Privacy Board has determined that the alteration or waiver of authorization, in whole or in part, satisfies the three criteria in the Rule;
- A brief description of the protected health information for which use or access has been determined to be necessary by the IRB or Privacy Board;
- A statement that the alteration or waiver of authorization has been reviewed and approved under either normal or expedited review procedures; and
- The signature of the chair or other member, as designated by the chair, of the IRB or the Privacy Board, as applicable.

The following three criteria must be satisfied for an IRB or Privacy Board to approve a waiver of authorization under the Privacy Rule:

- The use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements:
  - an adequate plan to protect the identifiers from improper use and disclosure;
  - 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
  - adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of protected health information would be permitted by this subpart;
- The research could not practicably be conducted without the waiver or alteration; and
- The research could not practicably be conducted without access to and use of the protected health information.

[iii] See Note ii above.

[iv] An authorization for the use or disclosure of PHI in a research study may be combined with other type of written permission for the same research study to create a compound authorization (e.g., informed consent).