		SOP
Department	**Title**	**Dates**
Research Integrity and Protection	Use/Disclosure of Protected Health Information for Research	Effective: 11/01/2017
		Approved: 10/25/2017
SOP ID		Last Revised: n/a
IRB-SOP-701		Expiration: n/a

PURPOSE

Ascension Wisconsin is committed to the protection of research participant's identifiable information in accordance to applicable federal and state laws, and ethical guidelines for research. This SOP describes the manner in which Protected Health Information (PHI) should be used or disclosed for research.

SCOPE

This SOP applies to all human subject research conducted within Ascension Wisconsin.

DEFINITIONS

Protected health information (PHI) Individually Identifiable Health Information, including demographic information, which relates to:

- the individual's past, present, or future physical or mental health or condition,
- the provision of health care to the individual, or
- the past, present, or future payment for the provision of health care to the individual, and that identifies the individual or for which there is a reasonable basis to believe can be used to identify the individual.

HIPAA Identifiers The HIPAA privacy rule sets forth policies to protect all individually identifiable health information that is held or transmitted by a covered entity. These are the 18 HIPAA Identifiers that are considered personally identifiable information.

De-Identified Health Information 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 per HHS Guidance; 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.

PROCESS

1. Except for reviews preparatory to research and research on decedents, PHI may be used or disclosed for purposes of research only with the subject's authorization, or if the IRB approves a waiver or alteration of subject authorization. This general rule does not apply to use of limited data sets or de-identified PHI.

2. Use/Disclosure of PHI Pursuant to Authorization

2.1. PHI may be used or disclosed for research purposes pursuant to a research participant's authorization that accords with the requirements of this policy.

2.2. An authorization for use and disclosure of PHI for a research purpose must include the following:

- a description of information to be used or disclosed;
- the name or other specific identification of the person(s) or class of persons authorized to make the requested use or disclosure;
- the name or other specific identification of the person(s) or class of persons to whom the Facility may make the requested use or disclosure;
- a description of each purpose of the requested use or disclosure;
- an expiration date or expiration event that relates to the individual or purpose of the use or disclosure, or a statement that there is no expiration;
- the signature of the individual and date, or, if the authorization is signed by a personal representative, a description of such representative's authority to act;
- a statement that the individual may revoke the authorization in writing, and either the exceptions to the right to revoke and instructions on how to exercise the right to revoke or, to the extent this information is included in organization's notice of privacy practices, a reference to the notice;
- a statement that information used or disclosed may be subject to re-disclosure by the recipient;
- a statement of the Facility's ability to condition research-related treatment on the authorization and the consequences of the individual's refusal to sign the authorization.

2.3. In general, the standard HIPAA authorization for the use or disclosure of PHI for research should be used. In rare cases, the IRB, as the HIPAA Privacy Board, may make an exception to allow the HIPAA authorization to be combined with consent to participate in the research.

2.4. A copy of the authorization must be given to the individual permitting the use or disclosure of his/her PHI.

3. IRB Waiver or Alteration of Authorization

3.1. An Investigator may request a waiver or alteration of authorization from the IRB, as the HIPAA Privacy Board, by submitting the request form with the IRB application.

3.2. An IRB waiver or alteration must include documentation of all of the following, and such documentation must be retained for at least six years after the date the study was completed:

3.2.1. Identification of the IRB;

3.2.2. Date on which the alteration or waiver was approved;

3.2.3. A statement that the IRB has determined that the proposed uses and disclosures of information involve no more than minimal risk to the privacy of individuals, based on the following:

- There is an adequate plan to protect the identifiers from improper use and disclosure;
- 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
- 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 law;

3.2.4. A statement that the research could not practicably be conducted without the waiver or alteration;

3.2.5. A statement that the research could not practicably be conducted without access to and use of the PHI;

3.2.6. A brief description of the protected health information that is necessary for the research;

3.2.7. A statement that the waiver or alteration has been approved under either normal or expedited review procedures; and

3.2.8. Signature of the chair, or other designated member, of the IRB.

3.3. IRB staff will provide written approval of the waiver or alteration. The use or disclosure of PHI for research pursuant to an IRB waiver or alteration of authorization may not begin until written approval obtained.

4. Review of PHI Preparatory to Research

4.1. Unless the research involves only decedents, as described below, a researcher who is affiliated with an Ascension Wisconsin Facility may review PHI solely to prepare a research protocol, or for similar purposes preparatory to research, without authorization or IRB waiver of authorization, provided that (s)he provides written representations in the IRB application that:

- the sole purpose of the review of PHI is to prepare a research protocol, or for similar purposes preparatory to research (e.g. to assist in the development of a research hypothesis or to aid in the recruitment of research participants), and the information will not be used for any other purpose;
- the PHI to be reviewed is necessary for these research purposes and only such PHI necessary for these purposes will be reviewed;
- no PHI will be removed from the premises;
- the information will not be released to a person not connected with the study; and
- the final product of the study will not reveal information that may serve to identify the patient whose records are being released without his/her informed consent.

4.2. Private pay patients may deny access to their PHI by annually submitting a signed, written request on a form provided by the Wisconsin Department of Health and Family Services.

5. Research Involving PHI of Decedents

5.1. A researcher affiliated with an Ascension Wisconsin Facility may review PHI of decedents without authorization or IRB waiver of authorization provided that (s)he provides the following:

- written representation that the use or disclosure being sought is solely for research on the PHI of decedents, and that the PHI being sought is necessary for the research and that the PHI will be used only for the indicated research;
- written representation that the information will not be released to a person not connected with the study;
- written representation that the final product of the research will not reveal information that may serve to identify the decedents whose records are being released; and
- documentation of the death of each individual whose PHI will be used or disclosed (excepting those individuals for which the Facility already has documentation of death).

5.2. This can be done by submitting the IRB form "HIPAA Decedent Certification Addendum"

5.3. IRB staff will provide written approval of the waiver or alteration. The use or disclosure of PHI for research may not begin until written approval obtained.

6. Inclusion of HIPAA authorization and/or Waivers of Authorization in the Medical Record

6.1. Documentation of the access, use or disclosure of PHI for research purposes must be documented in the subject's medical record. This includes access under the following methods:

- HIPAA authorization provided by research subjects
- Research reviews conducted under a waiver or alteration granted by the IRB (HIPAA Privacy Board for Research)

6.2. The investigator or their designee must submit a photocopy of the signed HIPAA Authorization to Health Information Management (HIM) at the study location. HIM is responsible for scanning the document into the medical record.

6.3. When the IRB grants a waiver or alteration of HIPAA Authorization, the access to PHI in the medical record may be documented by entering a note into the medical record which includes the reason for accessing the PHI and protocol number. Alternatively, investigator may work with HIM to get access to records. In those cases, the investigator or their designee must submit a photocopy of the IRB approval letter documenting the waiver was granted. HIM is responsible for scanning the document into the medical records accessed.

7. Accounting for Research Disclosures

7.1. The institution must document disclosures of PHI made for research purposes to meet regulatory requirements.

7.2. The Facility must maintain and provide to the individuals involved, upon their request, a list of such reviews that includes the following:

- the name of the protocol;
- a description of the protocol, including its purpose and inclusion criteria;
- a brief description of PHI disclosed;
- the time period during which disclosure occurred or may have occurred;
- contact information for the research sponsor, if any, and for person(s) who reviewed the PHI; and
- a statement that the PHI of the individual may or may not have been disclosed for the research activity.
- contact information for someone who can assist the individual in contacting the research sponsor and/or investigator(s) to whom PHI was disclosed, if requested.

8. Use/Disclosure of Limited Data Set

8.1. A limited data set may be used or disclosed for research purposes provided that the Facility and the recipient of the information have executed a data use agreement that complies with the provisions below.

8.2. A data use agreement must:

8.2.1. Establish the permitted uses and disclosures of the information by the recipient;

8.2.2. Establish who is permitted to use or disclose the data; and

8.2.3. Provide that the recipient will:

- not use or further disclose the information other than as permitted by the data use agreement or as otherwise required by law;
- use appropriate safeguards to prevent non-permitted use or disclosure of the limited data set information;
- report any use or disclosure of the information not provided for by the data use agreement of which it becomes aware;
- ensure that any agents to whom it provides the limited data set agree to the same restrictions and conditions that apply to the recipient; and
- not identify the information or contact the individuals.

9. Use/Disclosure of De-Identified PHI

9.1. The HIPAA Privacy Rule allows the use and/or disclosure of de-identified health information for research purposes.

9.2. The health information must be de-identified using either statistical verification of de-identification or by removing all 18 elements that could be used to identify the individual or the individual's relatives, employers, or household members. The requirements for statistical verification and the 18 elements are further described in the HIPAA privacy rule.

9.3. In addition, a code or other means of record identification may be assigned to de-identified PHI to allow for re-identification only if the following are true:

- The code or other means of record identification is not derived from or related to information about the patient and is not otherwise capable of being translated to identify the patient;
- The code or other means of record identification is not used or disclosed for any other purpose; and
- The mechanism for re-identification is not disclosed.

REFERNCES

HIPAA Privacy Rule (45 CFR Part 160 and Subparts A and E of Part 164)
HHS Guidance: "Guidance Regarding Methods for De-identification of Protected Health Information in Accordance with the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule"

RELATED MATERIAL

Ascension Wisconsin Policy: Confidentiality and Patient Privacy Rights With Regard to Protected Health Information

REVISION HISTORY

Version #	Date Revised	Reason for/Brief Description of Change	Revised By
01	10/23/2017	New- Initial Integration Update	J. Blundon