PURPOSE: To comply with HIPAA and other applicable law regarding the use and disclosure of Protected Health Information ("PHI") for research purposes.

POLICY: All Alexian Brothers Health System (ABHS) facilities may use and disclose PHI for research purposes only as specified in this policy.

SCOPE: All ABHS facilities.

DEFINITIONS:

Institutional Review Board (IRB): Either a committee group comprised of ABHS facility personnel and community representatives with varying backgrounds and professional experience, or a nationally recognized external IRB that review and approve research protocol involving human subjects.

Authorized User: An individual that is granted access to PHI for health care recipients through an authorization, IRB waiver or who is performing an activity related to health care operations.

Health Care Operations: Activities related to ABHS’ facilities functions as a health care provider, including general administrative and business functions necessary for the facilities to remain a viable health care provider.

De-Identified Health Information: Health information that has had all primary identifiers, such as the health care recipient’s name, address, date of birth (DOB), and secondary identifiers removed. This prevents anyone from deducing the health care recipient’s identity.

Limited Data Set: Is a compromise between PHI and de-identified information. It is a subset of PHI that excludes the direct identifiers but includes some secondary identifiers such as dates of service, age and some location information.

Protected Health Information (PHI): Individually identifiable health information transmitted or maintained in any form or medium, including oral, written, and electronic communications. Individually identifiable health information relates to a health care recipient’s health status or condition, furnishing health services to a health care recipient or paying or administering health care benefits to a health care recipient. Information is considered PHI where there is a reasonable basis to believe the information can be used to identify a health care recipient.
**Psychotherapy Notes:** Notes that are recorded (in any medium) by a health care provider, who is a mental health professional, documenting or analyzing the contents of conversation during a private counseling session or a group, joint, or family counseling session and that are separated from the rest of the health care recipient’s medical record.

**Workforce:** Employees, volunteers, trainees, and other persons whose conduct, in the performance of work for a covered entity, is under the direct control of such entity, whether or not they are paid by the covered entity.

**PROCEDURES:**

1) **Research Use or Disclosure of PHI With Authorization**
   
   a) 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. (Refer to Attachment A)

   b) An additional, separate authorization will be required if the research involves the use or disclosure of psychotherapy notes.

   c) An authorization for research must be written in plain language, and must contain all of the following elements:
      
      i) A specific and meaningful description of the information to be used or disclosed,

      ii) The name or identification of the persons or class of persons authorized to make disclosures of PHI and to use the PHI for research-related purposes;

      iii) The name or identification of the persons or class of persons authorized to receive disclosures of the PHI and to use the PHI for research-related purposes;

      iv) A description of each purpose of the use or disclosure;

      v) An expiration date or event, or a statement “end of research study” or “none” when appropriate (ex: for a research database);

      vi) The health care recipient’s signature (or that of his/her authorized representative as determined by state law) and date. (Note: if the authorization is signed by an authorized representative, include a description of the representative’s authority under state law to act for the health care recipient);

      vii) A statement that the health care recipient may revoke the authorization if done in writing to the principal investigator; however, the researcher may continue to use and disclose, for research integrity and reporting purposes, any PHI collected from the health care recipient pursuant to such authorization before it was revoked.

      viii) A statement that a health care recipient’s clinical treatment may not be conditioned upon whether or not the health care recipient signs the research authorization. However, participation in research may be conditioned on a signed authorization, including treatment protocols (ex: Phase III clinical trials).
ix) A statement that information disclosed under the authorization could potentially be redisclosed by the recipient and would no longer be protected under HIPAA.

d) The health care recipient must be provided with a copy of the signed authorization.

2) Procedure for Signing an Authorization
   a) Adults
      i) A competent health care recipient, 18 years of age or older, should always sign the authorization to use or disclose his/her PHI. A person is competent if he/she has the general ability to understand the concept of release of his/her medical information.

      ii) If a health care recipient is competent, but unable to sign the authorization, the person witnessing the form may write in “Health care recipient unable to sign due to __[insert reason]_____________. Health care recipient gave verbal permission.” The authorization must be witnessed.

      iii) If the health care recipient is not conscious, coherent or not competent for whatever reason, a legally recognized proxy must sign the authorization. ABHS facilities will follow the applicable state that defines order of individuals capable of serving as proxies. (Refer to Attachment B for state proxy orders)

   b) Minors
      i) Any parent may sign for a minor child in his/her legal custody;

      ii) Any minor who has been lawfully married and any minor parent or legal custodian of a child may sign for him/herself, his/her child and any child in his/her legal custody;

      iii) Any minor may sign for him/herself in case of:
          • Pregnancy, but excluding abortions;
          • Venereal disease;
          • Drug or substance abuse in accordance with state law.

      iv) Any adult standing in loco parentis, whether serving formally or not, may sign for his/her minor charge in case of emergency in accordance with state law.

3) Waiver of Authorization by IRB
   a) In some circumstances, research authorizations otherwise required under this policy may be waived or altered by the IRB, provided the following criteria are satisfied and documented:

      i) The use or disclosure of PHI involves no more than a minimal risk to the privacy of health care recipients, based on the presence of at least 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 the 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 PHI 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 PHI would be permitted by this policy;

      ii) The research could not practicably be conducted without the waiver; and
iii) The research could not *practically* be conducted without access to and use of the PHI.

b) A request for Waiver of Authorization must be completed by the researcher and submitted to the IRB for prior review and approval (Refer to Attachments C, D and E).

c) The IRB shall maintain the following documentation about the waiver:
   i) A statement identifying the IRB and the date on which the waiver request was approved;
   ii) A statement that the IRB determined that the waiver satisfied the criteria for waiver;
   iii) A statement that the waiver has been reviewed and approved under either normal or expedited review procedures; and
   iv) The documentation is signed by the IRB chair or his/her designee.
   v) The documentation will be kept for a minimum of 6 years.

d) Uses or disclosures of PHI made pursuant to a waiver are subject to the minimum necessary rules (Refer to ABHS “Minimum Necessary” policy).

e) If the Waiver of Authorization is approved by an external IRB, the facility’s Privacy Officer or designee will review the IRB’s documentation of the waiver for presence of the requirements listed above (a i – iii). Only waivers from IRBs that have been approved by an ABHS IRB will be approved.

f) If the Waiver of Authorization is for data analysis only and is not part of a study that involves interventions with human subjects, then the ABHS Privacy Officer will review and the waiver for the presence of the requirements listed above (a, i – iii) and it will not need IRB approval.

4) **Use and Disclosure of PHI for the Purpose of Contacting and/or Recruiting Potential Research Participants.**

   a) Physicians, and other health care providers, may contact their own health care recipients for purposes of recruiting them to participate in a research study without an authorization.

   b) Members of ABHS’ workforce may use ABHS PHI to contact prospective research subjects, provided all the requirements of Section 5 below, “Use and Disclosure of PHI Without Authorization Preparatory to Research,” are satisfied.

   c) Individuals responding to an advertisement regarding participation in a 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) prior to obtaining an authorization.

   d) An authorization must be obtained from an individual who has indicated interest in participating in a research study prior to asking the individual any screening questions that involve PHI.

   e) If treatment is conditioned on an authorization, the authorization must clearly distinguish between conditioned research components and non-conditioned components. The authorization must permit the health care recipient to opt-out of conditioned components.
f) An authorization for research purposes may be combined with other written permissions, including for uses and disclosures of PHI for data repositories or other databases.

g) An authorization may be used to permit use and disclosure of PHI for future research studies.

h) All other uses and disclosures of PHI for the purpose of contacting and/or recruiting potential research participants may require an authorization or waiver.

5) **Use and Disclosure of PHI Without Authorization Preparatory to Research**

a) Researchers, who are members of ABHS’ workforce, may use or disclose PHI without an authorization or IRB waiver for the development of a research protocol, provided that the researcher documents that all the following criteria are satisfied:

   i) The use or disclosure of PHI is solely to prepare a research protocol, or to identify prospective research participants for purposes of seeking an authorization;

   ii) The researcher shall not record or remove the PHI from ABHS and

   iii) The PHI sought is necessary for the purposes of the research.

b) The researcher will provide documentation to the data custodian that all of the above criteria are satisfied in accordance with the data management registration process of the individual business unit.

c) Uses or disclosures of PHI preparatory to research are subject to the minimum necessary rules (Refer to ABHS “Minimum Necessary” policy).

6) **Use and Disclosure of Decedent’s PHI Without an Authorization**

a) Researchers may use and disclose a decedent’s PHI for research without an authorization or IRB waiver, provided that the researcher documents that all the following criteria are satisfied:

   i) The use will be solely for research on the PHI of a decedent; and

   ii) The researcher has documentation of the death of the health care recipient about whom information is being sought, and

   iii) The PHI sought is necessary for the purposes of the research.

b) The researcher will provide documentation to the data custodian that all of the above criteria are satisfied in accordance with the data management registration process of the individual business unit.

c) Uses or disclosures of a decedent’s PHI for research purposes are subject to the minimum necessary rules (Refer to ABHS “Minimum Necessary” policy).

7) **Use or Disclosure of “De-Identified” Health Information**

a) De-identified health information is exempt from HIPAA and may be used or disclosed for research purposes without an authorization or IRB waiver. (Refer to ABHS “De-Identified Health Information” policy).
8) **Limited Data Set**
   a) A researcher may use or disclose a limited data set for any research purpose without an authorization or waiver. (Refer to ABHS “Limited Data Set” policy).

9) **Health Care Recipient’s Access to Research Information**
   a) As a general rule, health care recipients who participate in research have a right to access their own PHI that is maintained in a designated record set. (Refer to ABHS “Access to PHI” policy).

   b) However, health care recipients participating in research protocols that include treatment (ex: clinical trials) may be denied access to their PHI obtained in connection with that research protocol, provided that:
      i) The PHI was obtained in the course of the research;
      
      ii) The health care recipient agreed to the denial of access in the research authorization;
      
      iii) The research remains in process; and
      
      iv) The health care recipient’s rights to access such PHI are re-instated once the research study has ended and the research authorization has expired.

10) **Health Care Recipient’s Revocation of Research Authorization.**
    a) As a general rule, a health care recipient may revoke his/her authorization, in writing to the Principal Investigator, at any time.

    b) The revocation will be applicable to the protocol or protocols specified by the health care recipient. However, the researcher may continue to use and disclose, for research integrity and reporting purposes, any PHI collected about the health care recipient pursuant to a valid authorization before it was revoked.

    c) The Principal Investigator shall forward a copy of the written revocation to the facility Privacy Officer. The Principal Investigator shall also keep copies of all revocations of authorizations for a specific protocol, and report them to the IRB at the time of continuing review.

11) **Accounting of Disclosures.**
    a) As a general rule, a health care recipient must be provided with an accounting of all disclosures of his/her PHI for research purposes, unless such disclosure was made pursuant to an authorization, or is part of a limited data set. (Refer to ABHS “Accounting for Disclosure of Protected Health Information” policy).

    b) The researcher must keep records of all disclosures of PHI in the following circumstances:
        i) Disclosures pursuant to an IRB waiver;

        ii) Disclosures of PHI used in preparation of a research protocol; and

        iii) Disclosure of a decedent’s PHI used for research.

    c) A simplified accounting procedure may be used if the research use or disclosure involves the PHI of more than 50 people. Under the simplified accounting procedure:
        i) The health care recipient must be provided a list of research protocols in which the health care recipient’s PHI may have been used.
ii) The list must provide the following:
   • The name of the protocol or other research activity;
   • A description of the purpose of the study and the type of PHI disclosed; and
   • The timeframe during which such disclosures occurred.

iii) Upon request, the Privacy Officer, or his/her designee, will assist the health care recipient in contacting those researchers to whom it is likely that the health care recipient’s PHI was actually disclosed.

REFERENCES: 45 C.F.R. §160 and 164
Attachment A
ABHS Authorization Form for Use/Disclosure of Medical Information in Research

THIS PAGE IS NOT FOR THE RESEARCH PARTICIPANT
Implementation Instructions for a Stand-alone Authorization for Use and Disclosure of Health Information for Research Purposes (attached)

A copy of the signed Authorization must be provided to the research participant, once it is signed by the research participant.

NOTES: Obtaining the Authorization is the responsibility of the covered entity, i.e., the health care provider, pursuant to the requirements of the final HIPAA (Health Insurance Portability and Accountability Act of 1996) privacy regulation as provided in 45 CFR Parts 160 and 164. The Authorization is required to be obtained from a research participant enrolled in a research study AFTER the HIPAA compliance date of April 14, 2003 or if the research participant is re-consented (i.e., asked to sign a revised consent or another informed consent) AFTER April 14, 2003, unless an IRB or internal privacy board issues a waiver of authorization. The Authorization below is a stand-alone document but the Authorization may be combined with the research study informed consent. The Authorization must be “specific and meaningful” and in “plain language” so that the research participant has a meaningful understanding of how health information will be used and disclosed for purposes of the study.

Section 1: List the name of the entities or class of persons receiving the health information (“Receivers”); for example, name of sponsor of the research, name of the clinical research organization and the classes of the work force such as the study monitor, auditor, project manager, and those responsible for data management.

Section 2: Describe in detail the health information about the research participant to be used and disclosed.

Section 3: List the specific research purposes here for which the health information may be used and disclosed; for example, the health information about the research participant will be used for medical, statistical, and regulatory purposes related to the research.

Section 4: Not required, but recommended.

Section 6: Not required, but recommended to address parts of the “designated record set” (that is, the part of the medical record that is provided to the health care recipient when he / she requests a copy) that may be in the research study record and cannot be provided until after the study is over.

Section 7: Required statement.

Section 8: Rather than “no expiration date” (recommended), “end of study” can be stated as the date of expiration of the Authorization.

Section 9: Add the email address and street address of the Researchers’ business office, for which the privacy official manages the disclosure Authorizations.
Attachment A
ABHS Authorization Form for Use/Disclosure of Medical Information in Research

Authorization for Use and Disclosure of Health Information for Research Purposes

1. You agree to permit ________________________________ [Name of the Principal Investigator at the Site] and his/her staff, (“Researchers”) conducting the research study ____________________________________________ [title and description of research study], to use and disclose health information about you to the sponsor of the research ________________________________ [name of sponsor] and representatives of the sponsor ________________________________ [name of organization, e.g., contract research organization] assisting in the research (“Receivers”).

2. When we talk about health information about you to be used and disclosed, it includes all information about you collected during the research study for research purposes and the health information about you in medical records that is related to the research study. For example, it would include laboratory tests such as your blood counts and tests to measure the function of your liver and kidneys, x-rays or scans, and the following health information and tests:

______________________________________________________________________________
______________________________________________________________________________
______________________________________________________________________________

3. Health information about you may also be disclosed to and reviewed by an institutional review board, and representatives of government agencies, including the Food and Drug Administration (FDA) [and the Office of Human Research Protections, if applicable] and for the following purposes:

______________________________________________________________________________
______________________________________________________________________________
______________________________________________________________________________

If health information about you is required, the reviewers may need your entire medical record.

4. Health information about you may also be used to create information that does not identify you. The deidentified data may be used and released by Researchers, including use for other research purposes.

5. This health information about you may be further disclosed by the Receivers of the information. If disclosed by them, the information may no longer be covered by federal or state privacy regulations.

6. Information collected about you for purposes of this research study may be kept in a research study record separate from your medical records. You will not be able to obtain your research study record until the end of the study.

7. In order to participate in this research study, you must sign this Authorization. However, you cannot be denied medical treatment because you did not sign this Authorization.

8. This Authorization has no expiration date.
Attachment A  
ABHS Authorization Form for Use/Disclosure of Medical Information in Research

9. You have the right to revoke this Authorization at any time by a written notification to the Researchers’ Privacy Contact: ____________________________________________ If you revoke this Authorization, you will no longer be allowed to participate in the research. Also, even if you revoke this Authorization, the Researchers may still use and disclose the health information that they have already obtained as necessary to maintain the reliability of the research.

Signature of Research Participant  Date

Print Name of Research Participant

For Personal Representative of the Research Participant (if applicable)

Print Name of Personal Representative: ___________________________
Describe Personal Representative Relationship: ____________________________

(e.g., parent, guardian, power of attorney, etc.) I certify that I have the legal authority under applicable law to make this Authorization on behalf of the Research Participant identified above.

Signature of Personal Representative  Date
If the health care recipient is not conscious, coherent or competent for whatever reason, a legally recognized proxy must sign the authorization. ABHS facilities will allow the applicable state that defines order of individuals capable of serving as proxies.

The following order is accepted in the State of Illinois:

- Court appointed Guardian of the health care recipient;
- Spouse of the health care recipient;
- Adult son or daughter of the health care recipient;
- Either parent of the health care recipient;
- Adult brother or sister of the health care recipient;
- Adult grandchild of the health care recipient;
- Close friend of the health care recipient; or
- Health care recipient’s guardian of the estate.
Attachment C
ABHS PHI Authorization Waiver Application Form

In order to satisfy the requirements of ABHS HIPAA Compliance in Research Policy, please complete the form below. This information is required to obtain a waiver to access health care recipient’s Protected Health Information (PHI) without a prior authorization. Please refer to the policy for additional information on applying for a waiver. The completed form must be reviewed and approved before any access to PHI without a valid authorization will be granted. A separate document can be substituted for this form as long as all of the topics below are fully addressed.

Please explain how your research meets these criteria.

1. Research* and privacy risks are minimal

*the probability and magnitude of harm are not greater than those ordinarily encountered in daily life or during routine examinations

2. The waiver of consent will not adversely affect the rights and welfare of the participants.

3. Participant’s health information is protected against improper use or disclosure. Check all applicable statements.
   [ ] Research team members will sign a Confidentiality Agreement.
   [ ] The information will not be shared unless it is stripped of all PHI identifiers
      (See ABHS Policy Use and Disclosure of De-identified Protected Health Information)
   [ ] The information will be shared with a random code.

In addition, the Primary Investigator assures that:
• Only information essential to the purpose of the study will be collected.
• Access to the information will be limited to the greatest extent possible within the research team.
Attachment C
ABHS PHI Authorization Waiver Application Form

4. Data will be stripped of all identifiers upon completion of**:
   [ ] subject participation
   [ ] data analysis
   [ ] FDA approval
   [ ] specimen processing
   [ ] other (please specify):

OR

Identifiers will be retained indefinitely because:
   [ ] the study is longitudinal
   [ ] of federal requirements (specify):
   [ ] other ((please specify):

**Identifiers must be destroyed at the earliest opportunity consistent with the conduct of the research.

5. a) The research can not be practicably carried out without the Waiver of Consent.
   AND
   b) The research can not practicably be conducted without the participant’s PHI.
      [ ] PHI is needed to identify eligibility for the study
      [ ] PHI is the focus of the study (e.g. – epidemiological studies)
      [ ] Other (please specify):

6. [] The PHI required for the study qualifies as a Limited Data Set and will be used under a Data Use Agreement.

OR

[] Additional identifiers are required and must be used under a Waiver of Authorization with appropriate accounting procedures.

7. Whenever appropriate, subjects will be provided with additional pertinent information.

I verify that protected health information will not be re-used or disclosed to any other person or entity, except as required by law, research oversight, or those uses outlined above.

Applicant’s signature        Date
Attachment D
ABHS PHI Authorization Waiver Approval Form

___________(ABHS IRB or ABHS Privacy Officer)_____, has reviewed the Authorization Waiver application of ______________________ and has determined that it meets all criteria required to obtain a waiver to use or disclose Protected Health Information set forth in 45 CFR 160 and 164.

We have established:

1. The use or disclosure of PHI involves no more than a minimal risk to the privacy of health care recipients, based on the presence of the following elements:

2.
   a. An adequate plan to protect the identifiers from improper use and disclosure. ____ (initials)

   b. An adequate plan to destroy the identifiers at the earliest opportunity consistent with the conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law. _______ (initials)

   c. 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 PHI would be permitted by this waiver. ____ (initials)

3. The research could not practicably be conducted without the waiver ____ (initials)

4. The research could not practicably be conducted without access to and use of the PHI. ____ (initials)

This waiver was reviewed and approved under:

_____ normal review procedures

_____ expedited review procedures

This waiver is approved on ______________

Date

_________________________________ _______________
Signature Date

_________________________________ _________________
Please print name Title
Attachment E
ABHS PHI Authorization Waiver Denial Form

_____________________________ (ABHS IRB or ABHS Privacy Officer)______, has reviewed the protocol of __________________________ and has determined that it fails to meet all criteria required to obtain a waiver to use or disclose Protected Health Information set forth in 45 CFR 160 and 164.

The protocol does not meet the following criteria (check all that apply):
1. The use or disclosure of PHI involves no more than a minimal risk to the privacy of health care recipients, based on the presence of the following elements:
   a. An adequate plan to protect the identifiers from improper use and disclosure. ______
   b. An adequate plan to destroy the identifiers at the earliest opportunity consistent with the conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law. ____
   c. 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 PHI would be permitted by this waiver. _____
2. The research could not practicably be conducted without the waiver ______
3. The research could not practicably be conducted without access to and use of the PHI. _____

Please see our Policy for HIPAA Compliance in Research for guidance in completing a waiver application.

_________________________ _______________
Signature Date

_________________________ _______________
Please print name Title