POLICY TITLE: 401.00 Research Uses and Disclosures

Responsible Department: Corporate Privacy Office

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SUMMARY & PURPOSE:

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule provides Federal privacy protections for individually identifiable health information, called protected health information or PHI, held by most health care providers and health plans and their business associates. The HIPAA Privacy Rule protects all *"individually identifiable health information"* held or transmitted by a Baptist Health or its business associate, in any form or media, whether electronic, paper, or oral. The Privacy Rule sets out how and with whom PHI may be shared.

Baptist HealthSouth Florida has policies and procedures in place applicable to the access to and use of PHI that are consistent with applicable regulations and laws. Similarly, the Institutional Review Board ("IRB") has established policies and procedures to protect the privacy and information of potential, current, and former research participants at any Baptist Health facility.

POLICY:

It is the policy of Baptist Health South Florida, Inc. ("BHSF" or "Baptist Health") to comply with applicable state and federal laws, including those protecting the confidentiality of patient health information and establishing certain individual privacy rights. It is our policy to implement these laws in a way that supports our primary mission to the community regarding the delivery of quality health care in an efficient manner. This policy governs the uses and disclosures of patient information for research purposes which includes: The general rules for the use or disclosure of patient Information for research, reviews preparatory to research, confidentiality issues addressed in the research protocol application, use of a limited data set pursuant to a data use agreement, waiver of authorization to use and disclose patient information, research exempt from IRB review under the Common Rule, creation and use of databases / repositories for research analyses and accounting of disclosures of protected health information for research.

SCOPE/APPLICABILITY:

This policy applies to Baptist Health, its affiliates, all workforce members, and others as described below who proposes to conduct research involving Baptist Health patients or using patient information maintained by or on behalf of Baptist Health must submit a proposal to the IRB using the IRB research protocol application currently in effect prior to engaging in any research activities.

- **Workforce members.** Workforce members means employees, volunteers, trainees, temporary staff, and contractors/consultants who are not independent contractors under *Human Resources Policy 1150 - Independent Contractors.*

- **Medical staff members.** Medical staff members are treated as members of an organized health care arrangement with Baptist Health South Florida and must comply with this policy as if they are workforce members pursuant to their applicable medical staff bylaws.

- **Students.** Employed students are treated as workforce members. Non-employed students (fellows, residents, students) must comply with this policy as if they are workforce members pursuant to the terms of their applicable academic agreements.

- **Independent Contractors and Others.** Independent Contractors and others who have agreed to comply with Baptist Health's policies and procedures as a condition of receiving access to Protected Health Information (PHI) must comply with this policy as if they are workforce members.

DEFINITIONS:

1. Research: a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.
2. Authorization vs. Informed Consent
    a. Authorization is a written document that describes who may receive, use, and disclose participants' health information as part of the research, the purposes for which the information may be used and disclosed, and participants' rights with respect to these uses and disclosures of information. The obligation to obtain research participants' authorization is imposed by HIPAA.
    b. Informed consent is a process by which potential research participants are made aware of the purpose of the research, the procedures involved, the risks and potential benefits, and alternatives to participating in the research. The obligation to obtain research participants' informed consent is imposed by the Common Rule and other federal human subject research regulations, including FDA regulations.
    c. The informed consent and authorization requirements work independently. Investigators generally must obtain both from research participants, and an IRB waiver of informed consent will not automatically or necessarily result in an IRB waiver of authorization. Although informed consent will continue to include a discussion of participant confidentiality issues, this discussion will track the assurances given to participants in the HIPAA authorization document.
3. Limited Data Set
    a. A limited data set is information about a research participant that has been stripped of the following "direct" identifiers of the participant and the participant's relatives, household members, and employer(s):
        i. Names;
        ii. Postal address information, other than town or city, State, and zip code;
        iii. Telephone numbers;
        iv. Fax numbers;
        v. Electronic mail addresses;
        vi. Social security numbers;
        vii. Medical record numbers;
        viii. Health plan beneficiary numbers;
        ix. Account numbers;

x. Certificate/license numbers;
xi. Vehicle identifiers and serial numbers, including license plate numbers;
xii. Device identifiers and serial numbers;
xiii. Web Universal Resource Locators (URLs);
xiv. Internet Protocol (IP) address numbers;
xv. Biometric identifiers, including finger and voice prints; and
xvi. Full face photographic images and any comparable images.

b. A limited data set may not include any of the identifiers listed above. If the investigator indicates on the Research Protocol Application that he/she needs any of these identifiers, a Limited Data Set/Data Use Agreement may not be used and the limited data set may include only the minimum amount of patient information necessary for the purpose of the research. The IRB will evaluate the identifiers sought by the investigator to ensure that this standard is met.

4. Data Use Agreement:
   a. Describes the permitted uses and disclosures of the limited data set by the investigator (which may be only for the investigator's research, for public health activities, and/or Baptist Health's administrative activities) and states that the investigator will:
      i. Not use or further disclose the limited data set except as permitted by the Data Use Agreement or required by it.
      ii. Use appropriate protections to prevent any use or disclosure of the information that is not permitted by the Data Use Agreement.
      iii. Report to Baptist Health any known use or disclosure of the information that is not permitted by the Agreement.
      iv. Ensure that any agents, including subcontractors, to whom it provides the limited data set agree to the same restrictions that apply to the investigator.
      v. Not identify or contact the data subjects.
   b. Even if the individual requesting a limited data set from Baptist Health is an employee or a member of Baptist Health's workforce, a written Data Use Agreement, meeting the Privacy Rule requirements, must be in place between BHSF and the limited data set recipient.

PROCEDURES TO ENSURE COMPLIANCE:

1. General Rules for the Use or Disclosure of Patient Information for Research
   a. Baptist Health may use or disclose protected health information for research, regardless of the source of funding of the research, provided that:
      i. Baptist Health obtains documentation that an alteration to or waiver, in whole or in part, of the individual authorization required for use or disclosure of protected health information has been approved by either:
         1) An Institutional Review Board (IRB), or
         2) A privacy board that:
            a) Has members with varying backgrounds and appropriate professional competency as necessary to review the effect of the research protocol on the individual's privacy rights and related interests;
            b) Includes at least one member who is not affiliated with the covered entity, not affiliated with any entity conducting or sponsoring the research, and not related to any person who is affiliated with any of such entities; and
            c) Does not have any member participating in a review of any project in which the member has a conflict of interest.
      ii. Any Baptist Health employee, volunteer, workforce member, licensed health care professional or medical staff member who proposes to conduct research involving Baptist Health patients or using patient information maintained by or on behalf of Baptist Health shall submit a proposal to the IRB using the IRB research protocol application currently in effect.

iii. No person may conduct research involving Baptist Health patients or using patient information maintained by or on behalf of Baptist Health without submitting a completed research protocol application to the IRB.
iv. This includes, but is not limited to, persons who propose to conduct research that:
1) Is exempt from IRB review under the Federal Policy for the Protection of Human Subjects ("Common Rule") but involves Baptist Health patients or the creation or collection of patient information.
2) Involves patient information about deceased individuals; or
3) Involves the use of biological materials or tissues that can be linked to patient information.
v. The IRB will review the research protocol application in accordance with the IRB's policies and procedures.
vi. The privacy issues the IRB will consider in reviewing the research protocol application are described in section 3. This section should be carefully reviewed before completing and submitting the research protocol application to the IRB.

2. Access to Health Information
a. An individual's access to protected health information created or obtained by a covered health care provider in the course of research that includes treatment may be temporarily suspended for as long as the research is in progress, provided that the individual has agreed to the denial of access when consenting to participate in the research that includes treatment, and the covered health care provider has informed the individual that the right of access will be reinstated upon completion of the research.

3. Reviews Preparatory to Research
a. No person may review Baptist Health records containing patient information in preparation for research except as permitted by this policy.
b. This requirement applies even if the records pertain to patients that the reviewer and Baptist Health have in common. A clinician who wishes to review Baptist Health records relating to his or her own patients when preparing a research protocol may do so only as allowed by this policy.
c. Any person who seeks to review Baptist Health-maintained patient information for the purpose of preparing research must submit to the IRB a signed Investigator Certification for Reviews Preparatory to Research. In this Certification, the individual asserts that:
i. Access to the patient information is sought only for the purpose of developing a research protocol, evaluating Baptist Health as a clinical trial site, or identifying potential research participants;
ii. The requested information is necessary for this purpose; and
iii. No patient information will be copied or removed from the Baptist Health's facility's premises during or following the review. If an electronic record is accessed remotely, the patient information may be viewed but may not be printed, copied, downloaded, or otherwise recorded for any research-related purpose.
d. Acknowledgement by the IRB of receipt of a valid, completed Certification indicates approval of the request to conduct a records review. Note: The IRB may withhold or impose additional conditions on approval if, in the IRB's judgment, it is appropriate to do so.
e. Alternatively, if it is not possible to make the Certification described above, the person seeking to conduct a records review must obtain written documentation of a partial waiver of authorization by the IRB which permits the use or disclosure of the patient information for the limited purpose of a review preparatory to research. A Request for Partial Waiver of Authorization must be submitted to the IRB in the form designated by the IRB for this purpose. The IRB's written documentation of partial waiver indicates approval of the request to conduct a records review.

4. Confidentiality Issues Addressed in the Research Protocol Application
a. An investigator may not obtain, use, or disclose patient information for research purposes unless:
i. Each participant (or the participant's legal representative) signs a written authorization to use or disclose the participant's information for the research purpose;
ii. The information furnished to the investigator does not contain direct identifiers and the investigator signs a Baptist Health Data Use Agreement;
iii. The IRB waives the requirement to obtain authorization to use and disclose participants' information for the research purpose; or

iv. With respect to patient information about deceased individuals, the investigator makes certain representations to Baptist Health about the need to access and use information for the research purpose.

b. This requirement is in addition to the Common Rule requirement of informed consent to participate in research and is not affected by a decision by the IRB to waive informed consent.

c. The IRB anticipates that most investigators who propose to conduct research involving Baptist Health patients or using existing patient information about Baptist Health patients will obtain a written authorization from each participant (or their legal representative). However, for certain research studies that involve only reviews of existing records, the IRB may approve the use of a Data Use Agreement for a limited data set of information or, if the patient information concerns deceased individuals, accept a written certification from the investigator that access to the information is necessary for the research purpose. In very limited circumstances, the IRB may issue a waiver of authorization.

d. The investigator must indicate on the Research Protocol Application which form (or forms) of permission listed in Section 1 will provide the legal basis for accessing, using, and disclosing individuals' patient information as part of the proposed research.

5. Authorization to Use and Disclose Patient Information for Research

a. An authorization for the use or disclosure of protected health information for a research study may be combined with any other type of written permission for the same or another research study. This exception includes combining an authorization for the use or disclosure of protected health information for a research study with another authorization for the same research study, with an authorization for the creation or maintenance of a research database or repository, or with a consent to participate in research. Where a covered health care provider has conditioned the provision of research-related treatment on the provision of one of the authorizations, as permitted under the privacy rule, any compound authorization created must clearly differentiate between the conditioned and unconditioned components and provide the individual with an opportunity to opt-in to the research activities described in the unconditioned authorization.

b. A covered health care provider may condition the provision of research-related treatment on provision of an authorization for the use or disclosure of protected health information for such research.

c. The IRB will require investigators to obtain written authorization to use and disclose patient information for all clinical research and research involving questioning of the patient's or patients' physician(s) (e.g., survey research, genetic testing for research purposes).

d. The IRB also will require individual authorization for research that involves only a review of records containing existing patient information, unless:

i. Obtaining authorization is impractical under the circumstances; or

ii. The investigator needs access only to information that does not directly identify research participants.

e. Form of Authorization:

i. Investigators do not need to create a proposed authorization for review by the IRB. The IRB will require investigators to use an authorization required by the IRB. HIPAA establishes basic standards for the authorization, and investigators may not change the form's content without the prior express approval of the IRB.

ii. State health information privacy laws may require additional or stricter limitations on the use and disclosure of participants' information or give participants additional rights with respect to uses and disclosures of their information. The IRB may require the investigator to use a different form of authorization that satisfies the requirements of these laws.

iii. Where appropriate (for example, where the proposed research involves access to and use and/or disclosure of particularly sensitive information about participants), the IRB may require the investigator to use a different form of authorization that includes additional guarantees of confidentiality.

iv. Where appropriate, the IRB will require translations of the authorization document to be made available to potential study participants.

f. Process for Obtaining Authorization:

i. As with the informed consent form, the investigator and his/her staff must be prepared to explain to potential research participants the purpose of the authorization form and what its statements mean.

ii. The authorization form must be signed by the research participant or his or her legal representative. Unlike the Common Rule, which permits the IRB to waive the requirement for written documentation of informed consent under certain circumstances, the authorization must always be in writing.
iii. The research participant must be given a copy of the signed authorization at the time of signature.
iv. An expiration date or an expiration event that relates to the individual or the purpose of the use or disclosure. The statement "end of the research study," "none," or similar language is sufficient if the authorization is for a use or disclosure of protected health information for research, including for the creation and maintenance of a research database or research repository.
v. The investigator may use the authorization form to request patient information from a non-Baptist Health provider for use in research approved by the IRB.

6. Use of a limited Data Set Pursuant to a Data Use Agreement:
   a. Use of a limited data set and Data Use Agreement is appropriate when:
      i. The investigator does not need access to information that directly identifies the research participants; or
      ii. If individual authorizations or an IRB waiver of authorization will be obtained for a study and the investigator wishes to have the ability to re-analyze the research data for purposes that may be unrelated to the original protocol.
   b. Whenever feasible, use of a limited data set and Data Use Agreement is preferred over a waiver of authorization. When an investigator proposes to conduct research analyzing existing Baptist Health medical records, the IRB will consider whether the use of a limited data set and Data Use Agreement may be sufficient for the research purpose. Even where informed consent will be waived under the Common Rule, a Data Use Agreement is preferred to a waiver of authorization because it offers more protection for patient privacy and does not require Baptist Health to track disclosures of the information. An investigator who proposes to conduct data research based on a waiver of authorization must justify in the Research Protocol Application why a limited data set of patient information is not appropriate for the research purpose.
      i. A limited data set may not include any of the identifiers listed in the definitions section of this policy. If the investigator indicates on the Research Protocol Application that he/she needs any of these identifiers, a limited data set/Data Use Agreement may not be used; and
      ii. The limited data set may include only the minimum amount of patient information necessary for the purpose of the research. The IRB will evaluate the identifiers sought by the investigator to ensure that this standard is met.
      iii. Where the investigator proposes to retain and use a limited data set for future research, the investigator must indicate on the Research Protocol Application whether he/she:
         1) Will obtain study participants' written authorizations to create the limited data sets;
         2) Would like Baptist Health to create the limited data sets; or
         3) Will rely on a third party to create the limited data sets;
         4) If the investigator chooses option 3), he/she must attach to the Research Protocol Application a signed copy of a valid business associate agreement between Baptist Health and the third party which permits the third party to create limited data sets for Baptist Health.
   c. To access or receive the limited data set, the investigator must sign a Data Use Agreement with Baptist Health. The Data Use Agreement:
      i. Describes the permitted uses and disclosures of the limited data set by the investigator (which may be only for the investigator's research, for public health activities, and/or Baptist Health's administrative activities); and
      ii. States that the investigator will:
         1) Not use or further disclose the limited data set except as permitted by the Data Use Agreement or required by it;
         2) Use appropriate safeguards to prevent any use or disclosure of the information that is not permitted by the data use agreement;
         3) Report to Baptist Health any known use or disclosure of the information that is not permitted by the data use agreement;
         4) Ensure that any agents, including subcontractors, to whom it provides the limited data set agree to the same restrictions that apply to the investigator; and

5) Not identify or contact the data subjects.

d. Investigators do not need to attach a proposed Data Use Agreement for review by the IRB. The IRB will require all investigators using limited data sets for research purposes to sign Baptist Health's standard Data Use Agreement (investigators do not need to attach a copy of this form). The IRB will retain the signed, original data use agreement between the investigator and Baptist Health.

e. The IRB may require the investigator to sign a different version of the data use agreement which includes more restrictions on the use and disclosure of the limited data set or imposes more requirements on the investigator if the IRB determines that it is appropriate to do so because of the sensitivity of the information or the nature of the research.

f. Baptist Health is not in compliance with the Privacy Rule if it knows of a pattern of activity or practice of the limited data set recipient that constituted a material breach or violation of the data use agreement, unless the BHSF took reasonable steps to cure the breach or end the violation, as applicable, and, if such steps were unsuccessful:
   i. Discontinued disclosure of protected health information to the recipient; and
   ii. Reported the problem to the Secretary.

g. A covered entity that is a limited data set recipient and violates a data use agreement will be in noncompliance with the standards, implementation specifications, and requirements of the Privacy Rule.

7. Waiver of Authorization to Use and Disclose Patient Information:
   a. The IRB will grant a request to waive the authorization requirement only if:
      i. The use of a limited data set is inappropriate for the proposed research; and
      ii. The criteria listed below are met. A decision to waive authorization is made separately from a decision to waive the Common Rule requirement of informed consent to participate in research.
   b. Process for Review
      i. The IRB will follow its policies established under the Common Rule for deciding whether it will review a request for waiver of authorization under either normal or expedited review procedures.
   c. Criteria for Waiver of Authorization
      i. The IRB may approve a waiver of authorization, in whole or in part, if it determines that:
         1) The proposed use or disclosure of patient information involves only minimal risk to participants' privacy, as shown by at least the following:
            a) An adequate plan to protect identifiers from improper use and disclosure;
            b) An adequate plan to destroy the identifiers at the earliest opportunity (unless there is a health or research reason for keeping the identifiers, or if keeping the identifiers is required by law); and
            c) Adequate assurances that the patient information will not be re-used or disclosed to a third party except as required by law, for oversight of the research, or for other research for which authorization or waiver of authorization is obtained;
            d) The proposed research could not, as a practical matter, be conducted without the waiver or alteration; and
            e) The proposed research could not, as a practical matter, be conducted without access to and use of the patient information.
   d. In considering whether the proposed research poses "minimal risk" to participants' privacy, the IRB will take into account the three factors listed in *c.i.1.a-d* above (i.e., adequate plan to protect identifiers, adequate plan to destroy identifiers, and adequate assurances concerning re-use and disclosure) and may consider other factors as well (for example, whether the investigator's proposed protections are appropriate for the sensitivity of the information). The IRB also will consider the need for continued analysis of the data, the possibility that government agencies may need to review the research, and other factors when considering the investigator's plan for destruction of identifiers.
   e. The Privacy Rule requires that patient information made available under a waiver of authorization be the minimum necessary data for the research purpose. Although the IRB will not attempt to "second guess" which clinical and health data are necessary and appropriate for the research, it will consider this standard when determining which, if any, of the direct or indirect patient identifiers included in the definition of patient information may be necessary to the research.

f. State health information privacy laws may require the IRB to determine if additional criteria have been satisfied before approving a request for waiver of authorization.
g. Waivers of authorization are protocol-specific. The IRB will not approve a waiver request that will permit the investigator or another authorized recipient to use participants' information for any research purpose that is not part of the original protocol (including creation of a research database or repository for re-analysis unrelated to the protocol). With a waiver, however, the IRB may authorize the investigator and other data recipients to remove data that identify participants and to use and disclose the information that remains for any purpose permitted by law, including for other research purposes.

8. Use and Disclosure of Deceased Individuals' Information for Research Purposes
   a. HIPAA applies to information about deceased as well as living persons. Investigators may access, use, or disclose deceased individuals' information by obtaining authorization from the individuals' legal representatives or by obtaining an IRB waiver of authorization. Alternatively, the IRB may approve an investigator's request to access and use the information for research purposes based on a written certification that:
      i. Access to the requested information about the deceased persons is sought solely for the purpose of research using that information; and
      ii. The requested information is necessary for the research purpose.
   b. Certification Process:
      i. The investigator must indicate on the Research Protocol Application that he/she wishes to access information about deceased individuals on the basis of the representations described in Section 8a ;
      ii. The investigator must submit to the IRB a signed copy of the Investigator Certification for Research with Decedents' Information along with the Research Protocol Application;
      iii. At its option, the IRB may require the researcher to provide evidence (e.g., county or other public records) that the proposed data subjects are, in fact, deceased; and
      iv. If the IRB approves access by the investigator to the deceased individuals' information, the IRB will limit the amount of information made available to the minimum necessary for the research purpose.
   c. Contacting Potential Research Participants Clinical Trial Recruitment
      i. Without patient authorization or IRB waiver of authorization, the only persons who may use Baptist Health-maintained patient information to contact a current or former Baptist Health patient about a research opportunity are:
         1) Members of Baptist Health's workforce (employees, volunteers, workforce members); and
         2) Health care providers (licensed health care professionals and members of the medical staff) with current admitting privileges at Baptist Health who have or have had a treatment relationship with the patient (i.e., providers may not contact individuals whom they have not treated to discuss research opportunities).
      ii. The IRB generally will require that the research protocol rely on these persons to contact potential study participants.
      iii. In some instances, the IRB may grant a partial waiver of patient authorization which permits Baptist Health to disclose patients' patient information to other parties (e.g., third party investigators, clinicians with admitting privileges at Baptist Health who have not had a treatment relationship with the potential research participant) for the limited purpose of contacting patients about a research opportunity.
      iv. The investigator may request a partial waiver of patient authorization if he or she believes that the criteria for this waiver may be met.

9. Following Policy Procedures
   a. Any Baptist Health employee, volunteer, workforce member, licensed health care professional or medical staff member who wishes to review and/or use medical records, billing records, or other patient information maintained by or on behalf of Baptist Health for purposes of conducting research, developing research protocols or identifying potential participants for the research shall follow the procedures described in this policy for the Use or Disclosure of Patient Information for Research before beginning the following:.
      i. Research Exempt from IRB Review under the Common Rule
      ii. Clinical Research

iii. Research with Existing Data
iv. Using Deceased Individuals' Information
    1) For research on decedent's information, the covered entity must obtain the following from the researcher:
        a) Representation that the use or disclosure sought is solely for research on the protected health information of decedents;
        b) Documentation, at the request of the covered entity, of the death of such individuals; and
        c) Representation that the protected health information for which use or disclosure is sought is necessary for the research purposes.
v. Research with Biological Materials

10. Re-analysis of Research Data Obtained by Authorization or Waiver of Authorization
    a. Investigators who wish to re-analyze research data for purposes unrelated to the original protocol may do so only by following the procedures described below:
        i. De-identify the data before conducting the new analysis.
        ii. De-identify the data by following the de-identification procedure described in policy 10000-74220-206.00 Use and Disclosure Facially De-Identified Information and Data Use Agreements
        iii. Obtain new authorizations from participants which specifically permit use of the data for the new analysis.
        iv. Following the procedures described in this policy for the Use or Disclosure of Patient Information for Research, submit a new Research Protocol Application to the IRB before starting the new analysis.
        v. Obtain waiver of authorization which specifically permits use of the data for the new analysis.
            1) Following the procedures described in this policy for the Use or Disclosure of Patient Information for Research, submit a new Research Protocol Application to the IRB before starting the new analysis.
        vi. Sign a Data Use Agreement with Baptist Health which permits use of a limited data set of information about the study participants for any research purpose, including research unrelated to the original protocol.
            1) Sign a Data Use Agreement with Baptist Health at the time of IRB review of the initial research protocol, or, if a Data Use Agreement is not signed at that time, follow the procedures described in this policy for the Use or Disclosure of Patient Information for Research and submit a new Research Protocol Application to the IRB with a request for a Data Use Agreement with Baptist Health before starting the new analysis.
    b. Regardless when the investigator signs a Data Use Agreement with Baptist Health, the investigator must propose in the Research Protocol Application that the limited data set of patient information will be created by either:
        i. The investigator (but only with participants' written authorization to do so);
        ii. Baptist Health; or
        iii. A third party acting on behalf of Baptist Health.
    c. The investigator must attach to the Research Protocol Application a copy of a valid "business associate agreement" between the third party and Baptist Health which permits the third party to create limited data sets on Baptist Health's behalf.
11. Creation and Use of Databases / Repositories for Research Analyses
    a. An investigator who wishes to build or add to a database or repository of patient information must:
        i. Obtain a separate written authorization from each individual to whom the information refers which specifically permits the data to be included in the database or repository; or
        ii. Obtain a separate IRB waiver of authorization which specifically permits the data to be included in the database or repository.
    b. If the data to be stored in the database were originally obtained as part of a research study, this authorization or waiver of authorization must be separate from and in addition to the authorization or waiver, if any, to create or collect the information as part of the initial protocol.
    c. Each research-related use of patient information in the database or repository requires a new, separate authorization or IRB waiver of authorization.

d. The investigator must submit a new Research Protocol Application to the IRB for the proposed use of the research data.

12. Exception for Certain Previously-Approved Research Studies
    a. An investigator does not need to submit another Research Protocol Application for a protocol previously approved by the IRB if, before April 14, 2003, the investigator has obtained:
        i. An IRB-approved research informed consent from every participant in the study (i.e., enrollment closed before April 14, 2003).
        ii. An IRB waiver of informed consent that complies with the Common Rule; or
        iii. An authorization or other express legal permission from every participant in the study to use or disclose the participant's information for the research.
    b. It does not matter that the data collection phase of the research has not begun by April 14, 2003, so long as either (i), (ii), or (iii) is satisfied. However, Baptist Health and the investigator may use and disclose the patient information only to the extent and for the purpose(s) permitted by (i), (ii), or (iii) is (whichever is applicable). Furthermore, if the investigator wishes to obtain a new or revised informed consent from a study participant on or after April 14, 2003, the investigator must submit a new Research Protocol Application to the IRB and may not access, use, or disclose that participant's information without obtaining written authorization or IRB waiver of authorization.
    c. If a protocol has been approved by the IRB before April 14, 2003, but enrollment has not closed, the investigator may not access, use, or disclose patient information about any participant who signs an informed consent on or after that date without also obtaining written HIPAA authorization or IRB waiver of authorization. The investigator must submit a new Research Protocol Application to the IRB and must follow the procedures described in this policy with respect to that participant.
13. Accounting of Disclosures of Protected Health Information
    a. Baptist Health is responsible for tracking all disclosures of patient information to third party investigators based on the certification described in above or a partial waiver of authorization.
    b. The Privacy Rule allows three methods for accounting for research-related disclosures that are made without the individual's Authorization or other than a limited data set: (1) A standard approach, (2) a multiple-disclosures approach, and (3) an alternative for disclosures involving 50 or more individuals. Whatever approach is selected, the accounting is made in writing and provided to the requesting individual. Accounting reports to individuals may include results from more than one accounting method.
        i. Standard Accounting
            1) Standard accounting includes, for each disclosure, the following information:
                a) The date the disclosure was made.
                b) The name and, if known, address of the person or entity receiving the PHI.
                c) A brief description of the PHI disclosed.
                d) A brief statement of the reason for the disclosure.
            2) If the standard method is used, third party investigators must prepare and submit to the IRB at the time of the review a Record of Disclosure of Patient Information for each patient record reviewed.
            3) These forms shall be submitted to the Health Information Management Department of the appropriate Baptist Health facility for inclusion in the patient records.
        ii. Multiple Disclosures Accounting
            1) Multiple disclosures accounting is permissible if the covered entity has made multiple disclosures of PHI to the same person or entity for a single purpose under Sections the Privacy Rule. For each disclosure, the following must be included:
                a) The date the initial disclosure was made during the accounting period.
                b) The name and, if known, address of the person or entity receiving the PHI.
                c) A brief description of the PHI disclosed.
                d) A brief statement of the reason for the disclosure.
                e) The frequency, periodicity, or number of the disclosures made during the accounting period.
                f) The date of the last such disclosure during the accounting period.
        iii. Alternative Accounting
            1) If a covered entity has made disclosures regarding 50 or more individuals for a particular research project under of the Privacy Rule, the accounting may be limited to the following information:

a) The name of the protocol or research activity.
b) A plain-language description of the research protocol or activity, purpose of the research, and criteria for selecting particular records.
c) A description of the type of PHI disclosed.
d) The date or period of time during which the disclosure(s) occurred or may have occurred, including the date of the last disclosure during the accounting period.
e) The name, address, and telephone number of the entity that sponsored the research and of the researcher who received the PHI.
f) A statement that the individual's PHI may or may not have been disclosed for a particular protocol or research activity.

2) If the covered entity uses the alternative accounting method, it must, if requested to by the individual, assist the individual in contacting the research sponsor and the researcher. Such assistance, however, is limited to those situations in which there is a reasonable likelihood that the individual's PHI was actually disclosed for the research protocol or activity.

14. Documentation
    a. Baptist Health, as well as any other entity that provides patient information for research purposes, must retain a copy any required documentation a minimum of six (6) years from the date of IRB approval; or when the participant's information was last used or disclosed by Baptist Health pursuant to the waiver, whichever is later.

SUPPORTING/REFERENCE DOCUMENTATION:

- Health Insurance Portability and Accountability Act of 1996 as amended from time to time and including any regulations promulgated thereunder (collectively, "HIPAA")
- Department of Health and Human Services Part 46 – Protection of Human Subjects ("Common Rule")
- Applicable Florida State Laws

RELATED POLICIES, PROCEDURES AND ASSOCIATED FORMS:

- 10000-74220-001.00 Unified Corporate Privacy Policy on HIPAA Compliance
- Attachment - 10000-74220-6029 Record of Disclosures of Patient Health Information
- Institutional Review Board ('IRB') Policies 835.00-835.06.0

ENFORCEMENT & SANCTIONS:

1. Reference: Corporate HIPAA Privacy Policy 10000-74220-605.20 Sanctions for Privacy Violations
2. Violations of this policy will be determined by the Chief Privacy Officer in consultation with the appropriate levels of department leadership and appropriate Human Resources management level. Reference: HR policies 5250 Employee Conduct and 5300 Corrective Action.
3. Violations of this policy may lead to disciplinary action up to and including termination.
4. Enforcement of this policy will be performed by Baptist Health South Florida's Privacy Office in conjunction with Human Resources, as circumstances may dictate.