**PURPOSE**

To provide guidance on the use and/or disclosure of Protected Health Information (“PHI”) for research purposes.

**POLICY**

* [COVERED ENTITY] must obtain a patient’s authorization before releasing his/her PHI for research purposes.
* [COVERED ENTITY] will ensure that an appropriately instituted and formally designated (per Federal Drug Administration/FDA regulations) Institutional Review Board is utilized for the protection of human subjects in any research activity involving access to PHI under [COVERED ENTITY]’s control.
* The patient has the right to refuse to participate in research.
* [COVERED ENTITY] shall abide by the experimental subject’s (patient’s) privacy rights.

**PROCEDURE**

1. Federal regulations and state laws regulate the use of human subjects (patients) in any investigation designed to develop or contribute to specific knowledge. Such laws require that specific information be disclosed so that a subject (patient) may give informed authorization and that authorization must be documented.
2. At the beginning of any research project, [COVERED ENTITY] and the entity involved in the research must determine and agree on who will be responsible for obtaining an authorization to use or disclose PHI.
3. If an outside authorization is utilized, [COVERED ENTITY]’s Privacy Designee will review the patient’s authorization to assure that it is valid in accordance with the HIPAA Privacy Rules and those special provisions related to research.
4. Special Authorization Provisions Related to Research.
   1. *Expiration Date*: The Authorization form will state the expiration date or that the expiration event is “end of research study,” “none,” or similar language.
   2. *Combining Authorization*: The Authorization form may be combined with any other type of written permission for the same research study, including another authorization for the use or disclosure of PHI for such research or a consent to participate in such research.
   3. *Condition Treatment on Authorization*: The provision of research-related treatment may be conditioned on the provision of an authorization for the use or disclosure of PHI for such research.
5. Federal law requires the establishment of an Institutional Review Board (“IRB”) to review and approve proposed research and the process by which the investigator intends to secure the informed authorization of participants.
   1. Institutions engaged in research involving human subjects (e.g., medical schools, universities, large hospitals) will usually have their own IRB to oversee research conducted within the institution or by staff of the institution.
   2. It is the responsibility of the organization or institution conducting the research to establish or contract with an IRB; it is [COVERED ENTITY]’s responsibility to ensure that an IRB is utilized.
   3. If the research study is approved by the IRB and de-identified health information can be used or disclosed, then no further privacy implications exist. (See the Policy “De-Identification of Protected Health Information” for details of how to de-identify the health information for disclosure.)
   4. If the research study is approved by the IRB and de-identified health information cannot be used or disclosed, then an Authorization form is required and must be obtained from each patient included in the research study.
   5. Appropriate [COVERED ENTITY] staff will manage requests to participate in research studies and coordinate the review process by the IRB.
   6. Contact/communications with the IRB and related findings must be documented and communicated to [COVERED ENTITY]’s Privacy Officer.
6. If [COVERED ENTITY] participates in research projects, [COVERED ENTITY]’s Privacy Officer must have a method of tracking the correspondence, decisions, and other communications regarding the research project.
7. [COVERED ENTITY] will inform every patient of any research or economic interest (for example, any direct or indirect remuneration that may come to [COVERED ENTITY] as a result of the research) that may result from his or her treatment.
8. [COVERED ENTITY] or the entity conducting the research will obtain the patient’s Authorization form when required.
9. [COVERED ENTITY]’s Privacy Officer will file the original copy of the request and the associated response in the participant’s Medical Record.