Decatur Memorial Hospital

INSTITUTIONAL REVIEW BOARD
SOP 600: PRIVACY BOARD

POLICY

The Health Insurance Portability and Accountability Act ("HIPAA") generally requires specific compliance reviews and documentation by a Privacy Board in accordance with the HIPAA regulations when protected health information (PHI) is used and/or disclosed for research purposes. The Decatur Memorial Hospital Privacy Board plays a vital role in compliance with the HIPAA Privacy Rule (45 CFR 160 & 164) for the Heartland Cancer Research NCORP and Decatur Memorial Hospital on a whole.

The Decatur Memorial Hospital Institutional Review Board (IRB) will serve as the Privacy Board.

PROCEDURES

1. Authorization

1.1 An Authorization is an individual's signed permission to use or disclose the individual's PHI that is described in the Authorization for the purpose(s) and to the recipient(s) stated in the Authorization. In order to be valid, an Authorization must contain all the required elements and core statements outlined in the HIPAA Privacy Rule at 45 CFR 164.508(c). The signed Authorization must be retained for at least 6 years as per the privacy rule.

2. Principal Investigator (PI) Certification

2.1 The Certification is a letter signed by the PI. The Certification ensures that the PI will maintain, electronically and/or in hard copy, the signed Authorization for each research participant whose PHI is used or disclosed in the project and will provide any and/or all of the signed Authorizations to Decatur Memorial Hospital immediately upon request.

3. Composition of the Privacy Board

3.1 The Privacy Board will consist of at least five members and meet the requirements at section 164.512(i)(1)(i)(B). The members must have varying backgrounds and appropriate professional competencies as necessary to review the effect of a research protocol on the individual's privacy rights and related interests.

3.2 At least one member of a Privacy Board must be an independent member who is (1) not affiliated with the covered entity that will use or disclose the PHI in connection with the research project, (2) not affiliated with the entity conducting or sponsoring the research, and (3) not related to any person who is affiliated with the covered entity or the entities conducting or sponsoring the research.

4. Privacy Board Approval Proceedings

4.1 The HIPAA Authorization templates must be approved by a majority of the Privacy Board members present at the convened meeting.

4.2 No Privacy Board member may participate in the review of any project if that person has a conflict of interest.

5. Terms of Review

5.1 The Privacy Board shall meet, as necessary, to approve the stand-alone HIPAA Authorization templates. As revisions occur, the Privacy Board will convene to discuss and approve those changes.

6. Documentation of Approval

6.1 Approval of the HIPAA Authorization templates will be documented in the IRB meeting minutes.

SCOPE

This SOP applies to all Privacy Board members, IRB members, the IRB administrator, and Investigators.