Human Research Protections Institutional Review Board IRB 00001766

Statement of Compliance

The Decatur Memorial Hospital Institutional Review Board (IRB) is duly constituted, allows only those IRB members who are independent of the investigator and the sponsor of the trial to vote and provide opinion on the trial, has written procedures for initial and continuing review of clinical trials, prepares written minutes of convened meetings, and retains records pertaining to the review and approval process; all in compliance with the U.S. Department of Health and Human Services (DHHS) regulations 45 CFR Part 46, the U.S. Food and Drug Administration (FDA) regulations as described in 21 CFR Parts 50 and 56, and the guidelines of the International Conference on Harmonisation (ICH) relating to Good Clinical Practice (GCP).

The DMH IRB's primary responsibility is to protect the rights, welfare and safety of all human subjects participating in research.

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Christine Kraras, M.D. IRB Co-Chair