Statement of IRB Compliance

The Icahn School of Medicine at Mount Sinai and The Mount Sinai Hospital’s IRBs are duly constituted, allow only those IRB members who are independent of the investigator and the sponsor of the trial to vote/provide opinion on the trial, and have written procedures for initial and continuing review of human research protocols. The IRBs each comply with requirements defined in 45 CFR 46, 21 CFR 50 and 56, and ICH-GCP to the extent required by the U.S. Food and Drug Administration.