

## STATEMENT OF COMPLIANCE

Sterling Institutional Review Board (IRB) is duly constituted, 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.

Sterling IRB is organized and operates in compliance with the U.S. Department of Health and Human Services regulations 45 CFR Part 46, the U.S. Food and Drug Administration regulations as described in 21 CFR Parts 50 and 56, and adheres to the International Conference on Harmonisation (ICH) Good Clinical Practice (GCP) guidelines. Sterling IRB is registered with OHRP/FDA; our IRB registration number is IRB00001790, parent organization number is IORG0001354.

Where applicable, Sterling IRB complies with Part C Division 5 of the Canadian Food and Drug Regulations and the Tri-Council Policy Statement.

Since 2010, Sterling IRB has been fully accredited by the Association for the Accreditation of Human Research Protection Programs (AAHRPP).

Sterling Institutional Review Board's primary responsibility is to protect the privacy, safety and welfare of the human subject participating in research.



Kathye Richards, CIP, Institutional Official



Steven L. Saltzman, M.D., F.A.C.O.G., IRB Chairman