

THE UNIVERSITY OF TEXAS
SOUTHWESTERN MEDICAL CENTER
AT DALLAS

Institutional Review Board

October 5, 2009

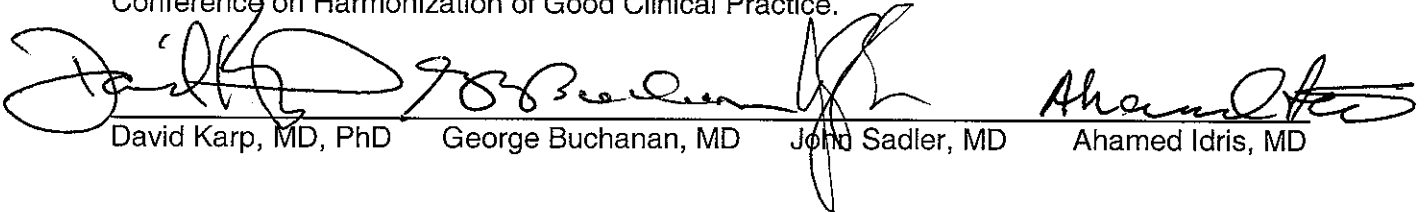
TO: Board Members, Principal Investigators and Research Coordinators

The University of Texas Southwestern Medical Center at Dallas (UT Southwestern) has a Federalwide Assurance on file with the Department of Health and Human Services (DHHS), in compliance with the requirements for the protection of human subjects in Research (Title 45 Code of Federal Regulations [CFR] Part 46, and all subparts otherwise known as "The Common Rule"). The current Assurance (FWA00005087) lasts three years and expires on October 5, 2012. Confirmation of this may be accessed at the following URL: http://www.hhs.gov/ohrp/assurances/assurances_index.html. UT Southwestern Institutional Review Board (IRB) is also in compliance with Title 21 CFR Parts 50 and 56 as well as all other Parts governing the use of investigational devices, drugs and biologics.

In addition to all components of UT Southwestern, the UT Southwestern IRB is the IRB of record for Parkland Health and Hospital System, Texas Scottish Rite Hospital for Children, UT Southwestern University Hospitals, Children's Medical Center, UT Southwestern Moncrief Cancer Center, and The Retina Foundation of the Southwest. The UT Southwestern IRB also reviews research conducted by Texas Health Presbyterian Hospital Dallas and the Dallas Veterans Affairs Medical Center when a member of the faculty of the University serves as principal investigator of the research.

The membership of the UT Southwestern IRB is in compliance with 45 CFR 46.107 and 21 CFR 56.107. The University and the UT Southwestern IRB assure compliance with 45 CFR 46.107(e) and 21 CFR 56.107(e), which states that "No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has conflicting interest, except to provide information requested by the IRB." The Board shall release the minutes and other written records of its meetings to duly authorized representatives of the federal government, upon request, to assure compliance with this regulation. The UT Southwestern IRB does not release the names of the members of the IRB to other parties out of respect for the privacy of the Board members.

The policies of the University and the IRB follow the guidelines of the International Conference on Harmonization of Good Clinical Practice.



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