March 4, 2015

To Whom It May Concern.

The University of Texas Southwestern Medical Center (UT Southwestern) does not release the names of its Institutional Review Board (IRB) members to anyone outside of the institution except federal regulatory agencies. UT Southwestern holds a current, approved Federal Assurance (FWA) of Compliance with the Department of Health and Human Services, which is not granted unless an institution’s IRB meets all requirements under 45 CFR Part 46. Hence, we provide our Assurance number (FWA00005087), rather than a list of IRB members when requested to confirm our compliance with applicable federal regulations. Our FWA expires on March 3, 2020.

UT Southwestern 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 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.” Any member of the IRB who is the Principal Investigator, Faculty Sponsor or a Co-Investigator on a protocol is prohibited from serving as a primary reviewer and must recuse him/herself from all IRB deliberations and voting relative to his/her project. IRB members are required to disclose such involvement in projects to be reviewed by the IRB and physically must leave the meeting room prior to the committee’s review of the research project in which the member is involved. 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 policies of the University and the IRB follow the guidelines of the International Conference on Harmonization of Good Clinical Practices.

If you have any questions regarding the protection of human research subjects at UT Southwestern Medical Center, please contact me at 214-648-0456.

Sincerely,

Angela Wishon, J.D.
Vice President for Research Administration