

CO 601-K

01/01/07

Print letter on SHS IRRC/Research letterhead

(Date)

To Whom It May Concern:

This letter will serve to certify that the Sparrow Health System's Institutional Research Review Committee (IRB), located at 1215 E Michigan Avenue, Lansing, Michigan 48912, is organized and operates according to Good Clinical Practices, and applicable federal and local laws and regulations (DHHS Federal Policy for Protection of Human Subjects 45 CFR 46, and FDA Regulations pertaining to research with human subjects, 21 CFR 56). The IRB carries a Federal Wide Assurance (FWA #00003015 and is registered with OHRP as IRB #00002443) which ensures that we are routinely audited for compliance with the above regulations. Please refer to OHRP's Web site at http://www.hhs.gov/ohrp/assurances/assurances_index.html.

With regard to IRB review of protocols, the following excerpt is taken from the Sparrow Health System's Institutional Research Review Committee's Policies and Procedures:

“Members with a conflict of interest will recuse themselves from the discussion and voting and such will be noted in the minutes.”

If you require further information regarding the Sparrow Health System's Institutional Research Review Committee's compliance with federal regulations, please contact George S. Abela, MD, IRB Chairperson at 517.364.2157.

Sincerely,

George S. Abela, MD
IRB Chairperson

Suzanne Leialoha, CIM
IRB Administrator

Enclosure: Roster List of IRB Members