

Statement of Compliance

Schulman Associates Institutional Review Board, Inc. (Schulman) is in compliance with the regulations of the United States Food and Drug Administration as described in 21 CFR Parts 50 and 56, the International Conference on Harmonization Good Clinical Practice Guidelines and, as applicable, the United States Department of Health and Human Services regulations 45 CFR Part 46, Part C Division 5 of the Canadian Food and Drug Regulations and the Tri-Council Policy Statement.

In June of 2008, Schulman was awarded a full three year accreditation by the Association for the Accreditation of Human Research Protection Programs. Schulman was previously accredited in June of 2005 by the Partnership for Human Research Protection. Schulman's commitment to the accreditation process demonstrates its commitment to research ethics and human subject protection.

Schulman's IRB operates in compliance with all relevant federal and local regulations and is registered with FDA. Schulman's IRB Organization number is 0000635. Schulman's IRB registration number is 00000971 (effective through July 31, 2012). Please note that this IRB registration number applies for both FDA and OHRP registrations.