



Statement of Compliance

To Whom It May Concern:

In addition to the Department of Health and Human Services (DHHS) Federalwide Assurance of Compliance number FWA 00003937 (compliance with 45 CFR 46), the University Hospitals Case Medical Center (UHCMC) Institutional Review Boards (IRB) for Human Investigation (registration numbers 00000684 and 00001691) adheres to the U.S Food and Drug Administration (FDA) regulations promulgated under 21 CFR 50, 56, 312 and 812. Investigators will receive a formal certification of IRB review under these regulations upon IRB approval of the research project.

The UHCMC IRB is duly constituted, fulfilling all the requirements for diversity, and has written procedures for initial and continuing review for all human research protocols.

In addition the UHCMC IRB complies with the guidelines established under Good Clinical Practices (GCP) and the International Conference on Harmonization (ICH) to the extent required by the U.S. Food and Drug Administration.

A handwritten signature in black ink that reads 'Philip A. Cola'.

Philip A. Cola, M.A.
Vice President for Research and Technology,
Center for Clinical Research and Technology
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