

February 11, 2009

To Whom It May Concern:

To be in compliance with 45 CFR Part 46 Subparts A-D, Wayne State University (WSU) operates under a Federal Wide Assurance (FWA) with the United States Department of Health and Human Services. This document (FWA #00002460) is on file with the Office for Human Research Protection and will expire on **January 15, 2012**.

There are six Institutional Review Boards (IRBs) at WSU that review all human research submissions. They are:

M1-Medical- #00000325
MP2-Medical-Pediatrics-# 00000326
B3-Behavioral- #00000327
MP4-Medical-Pediatrics # 00000328
CTS1-# 00006470
PH1- Medical Phase 1 # 00006856

In the role of protecting human participants, the IRB Chairs report to the Chair of the Human Investigation Committee (HIC) at WSU. The Chair of the HIC is authorized to give assurances concerning compliance.

The six IRBs at WSU are in compliance with the U.S. Department of Food and Drug Administration (FDA) under 21 CFR 50, 21 CFR 56, 21 CFR 312, 21 CFR 812 & 21 CFR 814.

The six IRBs at WSU are in compliance with 38 CFR 16, Protection of Human Subjects, the Common Rule codified for the U.S. Department of Veterans Affairs.

The six IRBs at WSU are in compliance with 45 CFR 160 and 164 (A, E), the Privacy Rule codified by the Health Insurance Portability and Accountability Act (HIPAA) of 1996 and serve as the Privacy Boards for research conducted at WSU and its affiliate institutions.

In addition, the six IRBs at WSU comply with the Good Clinical Practice Guidelines of the International Conference on Harmonization to the extent required by the U.S. Food and Drug Administration.


James E. Puklin, MD, Chair, Human Investigation Committee


Date