

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.

There are five 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

PH1- Medical Phase 1 # 00006856

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

The five 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 five 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 five 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.

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Vice President for Research

Wayne State University

date

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