



**WAYNE STATE  
UNIVERSITY**  
Division of Research  
& Innovation

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December 3, 2024

Wayne State University (WSU) operates under a Federal Wide Assurance (FWA), #00002460, with the United States Department of Health and Human Services, Office for Human Research Protection, in compliance with 45 CFR Part 46.

The WSU Human Research Protection Program, including its IRBs, are fully accredited by the Association for the Accreditation of Human Research Protection Programs (AAHRPP) and are regularly inspected by the U.S. FDA. The Institutional Review Boards (IRBs) include:

- M1 IRB #00000325: Medical
- MP2 IRB #00000326 Medical/Pediatric
- B3 IRB #00000327 Social/Behavioral/Education

When applicable, the WSU IRBs are in compliance with the following:

1. Code of Federal Regulations, Title 45, Subtitle A, Subchapter A - Department of Health and Human Services: 45 CFR 46, Protection of Human Subjects.
2. Code of Federal Regulations Title 21, Chapter I – Food and Drug Administration: 21 CFR 50, 21 CFR 56, 21 CFR 312, 21 CFR 812 and 21 CFR 814.Subpart H.
3. Code of Federal Regulations, Title 38, Chapter I – Department of Federal Affairs: 38 CFR 16, Protection of Human Subjects.
4. Code of Federal Regulations Title 28, Chapter I - Department of Justice: 28 CFR 46, Protection of Human Subjects.
5. Health Insurance Portability and Accountability Act of 1996 (HIPAA), 45CFR 60 and 164 (A.E), and serve as the Privacy Boards for research conducted at WSU and its affiliate institutions.
6. International Conference on Harmonization - Good Clinical Practice Guidelines (ICH-GCP) when required by a sponsor to the extent the guidelines are compatible with FDA regulations.

Sincerely,

Philip R. Cunningham, Ph.D.