



WAYNE STATE UNIVERSITY

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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:

Medical: M1 IRB #00000325; MP2 IRB #00000326; PH1 IRB #00006856

Social/Behavioral/Education: B3 IRB #00000327

The WSU IRBs are in compliance with the:

- 1) 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.
- 2) Code of Federal Regulations, Title 38, Chapter I – Department of Federal Affairs: 38 CFR 16, Protection of Human Subjects.
- 3) 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.
- 4) Good Clinical Practice Guidelines of the International Conference on Harmonization (GCP-ICH) to the extent required by the U.S. Food and Drug Administration.

A handwritten signature in black ink, appearing to read 'Stephen M. Lanier'.

12/02/19

Stephen M. Lanier, Ph.D.
Professor of Pharmacology
Vice President for Research
Wayne State University

Date