McLaren HEALTH CARE

MEMORANDUM

TO: WHOM IT MAY CONCERN
FROM: Chandan Gupte
Corporate Vice President
Clinical Excellence & Research

SUBJECT: ASSURANCE OF COMPLIANCE

The Institutional Review Board of the McLaren's Healthcare Corporation (MHC IRB) is organized and operates in compliance with the McLaren's Institutional policies for the conduct of human subject research, State of Michigan law, U.S. Department of Health & Human Services (DHHS) regulations 45 CR 46, Food & Drug Administration (FDA) regulations 21 CFR Parts 50 / 56 for the protection of human subjects and Good Clinical Practice (GCP), as applicable. MHC IRB has written policies and procedures in place for initial and continuing review and changes to currently approved protocols; prepares written minutes of convened meeting and retains records pertaining to the review and approval process.

MHC IRB is registered with OHRP/FDA and functions under Registration Number IRB00008640 and Parent Organization Number 0007199. McLaren Health Care (MHC) includes 10 subsidiary hospitals which conduct research under one centralized corporate institutional review board. MHC has one Federal-Wide Assurance (FWA) on which each subsidiary is listed as a component. McLaren's Human Research Protection Program (HRPP) is a centralized system to ensure the protection of the rights and welfare of subjects and compliance with the highest legal and ethical standards in human research. McLaren's approved FWA from DHHS, signifies that our Institution operates in total compliance with regulations concerning the protection of human subjects.

McLaren's Human Research Protections Program, including MHC IRB has received Full Accreditation by the Association for the Accreditation of Human Research Protection Programs (AAHRPP) at its December 2013 Council meeting.

If you have any questions or require additional information, please do not hesitate to contact us.

RESEARCH INTEGRITY

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