Unaffiliated Individual Investigator Agreement

Please type your responses.

Unaffiliated Individual Investigator Request to Conduct Research at McLaren Health Care	
Name (last, first, middle)	
Degree	
Address	
Email address	
Phone number	
Place of employment	
Primary Investigator of Research Study	
IRB Protocol Number	
Research Study Title	
Describe role and responsibilities in research project:	

McLaren
HEALTH CARE

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Obligations and Commitments of Unaffiliated Investigator

In the performance of research activities at McLaren, Investigator agrees to the following obligations and makes the following commitments:

(1) The Investigator has reviewed and agrees to abide by: (a) *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (or other internationally recognized equivalent: see section B.1. of the Terms of the Federalwide Assurance (FWA) for International (Non-U.S.) Institutions); (b) the U.S. Department of Health and Human Services (HHS) regulations for the protection of human subjects at 45 CFR part 46, and all Subparts (c) the U.S. Food and Drug Administration (FDA) regulations for the protection of human subjects at 21 CFR part 50; (d) McLaren policies and procedures for the protection of human research participants and their protected health information.

(2) The Investigator understands and hereby accepts the responsibility to comply with the standards and requirements stipulated in the above documents and to protect the rights and welfare of human subjects involved in research conducted under this Agreement.

(3) The Investigator will comply with all other applicable federal, international, state, and local laws, regulations, and policies that may provide additional protection for individuals participating in research conducted under this Agreement, including, but not limited to, HIPAA's Privacy and Security Rules and the requirements governing the use and disclosure of Protected Health Information in research.

(4) The Investigator will abide by all determinations of the Institutional Review Board of record for the Study (the "IRB") and will accept the final authority and decisions of the IRB, including but not limited to directives to terminate participation in designated research activities. The Investigator will not commence the Study without the prior approval of the IRB, and the Investigator will not initiate changes in the Study without prior IRB review and approval, except where necessary to eliminate apparent immediate hazards to subjects.

(5) The Investigator has completed MHC IRB required CITI courses Human Subject Research and Conflict of Interest prior to commencing research activities associated with the Study.

(6) The Investigator will report immediately to the Principal Investigator and the IRB any unanticipated problems involving risks to subjects or others arising from the Study.

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(7) If the Investigator is involved in enrolling research participants in the Study, the Investigator will obtain, document, and maintain records of informed consent for each person enrolled or each person's legally authorized representative as required under HHS regulations at 45 CFR part 46 (or any other international or national procedural standards selected on the FWA referenced above), consistently with the IRB-approved protocol and as required by the IRB.

(8) The Investigator acknowledges and agrees to cooperate in assisting the IRB in fulfilling its responsibility for initial and continuing review, record keeping, reporting, auditing, monitoring, and certification for the research referenced above. The Investigator will provide all information requested by the IRB in a timely fashion.

(9) The Investigator acknowledges that he/she is responsible for safeguarding the rights and welfare of each research participant and that each subject's rights and welfare are paramount to and must take precedence over the goals and requirements of the research.

(10) Emergency medical care may be delivered without IRB review and approval.

(11) Investigator has provided up-to-date, complete, and correct information about the Study in its submission of this Application, along with up-to-date, complete and correct copies of the Investigator Curriculum Vitae and professional license(s), if applicable.

Unaffiliated Individual Investigator Signature:

Signed: _____ Date _____

Printed Name: _____

Please Attachment:

☐ **Current CV or Resume**
☐ **Current License (for professions that require licenses)**

APPROVAL OF REQUEST IS EFFECTIVE ON THE DATE SIGNED BELOW.

McLaren Health Care Institutional Signatory Official (or designee):

Signed: _____ Date _____

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Printed Name: _____