THE UNIVERSITY OF MICHIGAN REGENTS COMMUNICATION

ACTION REQUEST

Subject: Subcontract Agreement between the University of Michigan and

MDI Therapeutics, Inc.

Action Requested: Authorization to enter into Agreement

Preamble:

A statutory conflict of interest situation was identified by the Office of Research and Sponsored Projects while reviewing the Proposal Approval Form which then triggered a review by the Medical School Conflict of Interest Board. A plan for management of the possible risks associated with the conflict of interest was then developed and approved by the Board and agreed to by the parties involved.

This proposed agreement ("Agreement") falls under the State of Michigan Conflict of Interest Statute because Professors Daniel Lawrence, Maria Sandkvist, and Enming (Joseph) Su are employees of the University of Michigan ("University"), and partial owners of MDI Therapeutics, Inc., formerly known as MedigenixBio, Inc. The law permits such an Agreement provided it is disclosed to the Board of Regents ("Regents") of the University of Michigan and approved in advance by a 2/3 vote.

Background:

Daniel Lawrence, PhD, a Professor in the Department of Internal Medicine – Cardiology and Cardiovascular Medicine, Maria Sandkvist, PhD, an Associate Professor in the Department of Microbiology and Immunology, and Enming (Joseph) Su, PhD, an Associate Research Scientist in the Department of Internal Medicine – Cardiovascular Medicine, are partial owners of a for-profit company called MDI Therapeutics, Inc. (the "Company"). The Company wishes to fund a NIH (prime) SBIR Phase I project entitled "Development of a Small Molecule Inhibitor of PAI-1 for the Treatment of Diffuse Cutaneous Systemic Sclerosis" (ORSP #18-PAF04039) in the Department of Internal Medicine – Cardiology under the direction of Dr. Daniel Lawrence. The purpose of this project is to provide critical preclinical data for a novel therapeutic small molecule inhibitor of plasminogen activator inhibitor 1 (PAI-1) as a potential treatment for diffuse cutaneous systemic sclerosis with associated interstitial lung disease ("dcSSc-ILD").

Agreement Terms:

The terms of the Agreement conform to University policy. The period of performance for the project is approximately six (6) months. The amount of funding support will not exceed \$74,140. Since research projects are often amended, this agreement includes provisions for changes in time and scope. University procedures for approval of these changes will be followed and additional conflict of interest review will be done as appropriate.

<u>Impact of the Agreement:</u>

The Agreement will support an effort by Dr. Lawrence to use his expertise and University laboratory, as well as other University resources, to design experiments, perform them, and interpret data relative to a potential treatment for dcSSc-ILD.

Recommendations:

This matter has been reviewed and approved by the Medical School Conflict of Interest Board. In light of this disclosure and our finding that the Agreement was negotiated in conformance with standard University practices, I <u>recommend</u> that the Board of Regents approve the University's entering into this Agreement with MDI Therapeutics, Inc.

Respectfully submitted,

S. Jack Hu

Vice President for Research

February 2018