# 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 Professor Daniel Lawrence and Dr. Enming Su are employees of the University of Michigan ("University"), and partial owners of MDI Therapeutics, 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 – Cardiovascular Medicine, and Enming Su, PhD, an Associate Research Scientist in the Department of Internal Medicine – Cardiovascular Medicine, are the partial owners of a for-profit company called MDI Therapeutics, Inc. (the "Company"). The Company wishes to fund an NIH (prime) SBIR Phase II project entitled, "Development of a Small Molecule Inhibitor of PAI-1 for the Treatment of Diffuse Cutaneous Systemic Sclerosis – Phase II" (ORSP #19-PAF06283) in the Department of Internal Medicine – Cardiovascular Medicine, under the direction of Dr. Lawrence. The purpose of this project is to examine the role of PAI-1 in the mouse models of scleroderma and to investigate the effects of PAI-1 expression or PAI-1 inhibition of the expression of pro-fibrotic genes in vivo and in cell culture.

### **Agreement Terms:**

The terms of the Agreement conform to University policy. The period of performance for the project is approximately two (2) years. The amount of funding support will not exceed \$245,894. 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.

## **Impact of the Agreement:**

The Agreement will support an effort by Dr. Lawrence to use his expertise and University laboratory, as well as other University resources, to examine the role of PAI-1 in the mouse models of scleroderma and to investigate the effects of PAI-1 expression or PAI-1 inhibition of the expression of pro-fibrotic genes in vivo and in cell culture.

## 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

May 2019