THE UNIVERSITY OF MICHIGAN REGENTS COMMUNICATION

ACTION REQUEST

Subject:	Research Agreement	between t	the	University	of Michigan	and
	The Hope Foundation	1				

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 research agreement ("Agreement") falls under the State of Michigan Conflict of Interest Statute because Professor James Rae is an employee of the University of Michigan ("University"), and Secretary of the Board of Directors for The Hope Foundation. 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:

James Rae, PhD, a Professor in the Department of Internal Medicine, is the Secretary of the Board of Directors for a non-profit foundation called The Hope Foundation (the "Company"). The Company wishes to fund a project entitled "Vitamin D Deficiency and Risk of Paclitaxel-induced Peripheral Neuropathy in Patients on SWOG 0221" (ORSP #20-PAF05427) in the Department of Clinical Pharmacy under the direction of Dr. Daniel Hertz. The purpose of this project is to optimize paclitaxel treatment outcomes in patients with early stage breast cancer.

Agreement Terms:

The terms of the Agreement conform to University policy. The period of performance for the project is approximately one (1) year. The amount of funding support will not exceed \$174,920. Since research projects are often amended, this agreement includes a provision 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. Hertz to use his expertise and University laboratory, as well as other University resources, to confirm findings that pre-treatment vitamin D deficiency increases peripheral neuropathy (PN) risk and that vitamin D deficiency mediates PN protection from multivitamin use.

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 The Hope Foundation.

Respectfully submitted,

Inhum

Rebecca Cunningham Interim Vice President for Research

March 2020