

THE UNIVERSITY OF MICHIGAN  
REGENTS COMMUNICATION

ACTION REQUEST

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

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 “Pilot Study to determine analytic validity of characterizing circulating tumor cells (CTC) in cerebrospinal fluid (CSF-TC) for ER and HER2 and comparison of genomic profiling of DNA derived from CSF-TC those of CTC DNA from blood in cancer patients with leptomeningeal metastasis” (ORSP #18-PAF08137), in the Department of Internal Medicine-Hematology/Oncology under the direction of Dr. Costanza Paoletti. The purpose of this project is to compare the genomic profiles of circulating tumor cells from cerebrospinal fluid and circulating tumor cells in blood to those of circulating free DNA from cerebrospinal fluid and blood.

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 \$62,500. 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. Costanza Paoletti to use her expertise and University laboratory, as well as other University resources, to demonstrate the potential utility of cerebrospinal fluid circulating biomarker and its incorporation into therapeutic decision making in breast cancer patients with leptomeningeal metastasis as well as generate preliminary data to examine the clinical validity of circulating biomarker in the cerebrospinal fluid.

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 recommend that the Board of Regents approve the University's entering into this Agreement with The Hope Foundation.

Respectfully submitted,

A handwritten signature in blue ink, appearing to read 'S. Hu', is positioned above the printed name.

S. Jack Hu  
Vice President for Research

July 2018