

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 M. 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 M. Rae, PhD, a Professor in the Department of Internal Medicine – Hematology/Oncology, 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 “BIOmaker driven immune CHECKpoint inhibitor therapy in metastatic breast cancer (BIO-CHECK)” (ORSP #18-PAF05515), in the Department of Internal Medicine – Hematology/Oncology under the direction of Dr. Erin Cobain. The purpose of this project is to study the efficacy of dual checkpoint blockade (CTLA-4 and PD-L1 inhibition) in chemotherapy-refractory metastatic breast cancer (MBC) and chemo-immunotherapy in chemotherapy-sensitive MBC and identify biomarkers predictive of benefit from immune checkpoint inhibitors in MBC.

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 \$100,000. 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. Cobain to use her expertise and University laboratory, as well as other University resources, to determine if dual immune checkpoint inhibition may improve overall survival in patients with chemotherapy refractory metastatic breast cancer (MBC), determine which chemotherapy agent is most immunogenic, and determine if several tumor biomarkers may be prognostic of benefit from immune checkpoint inhibitor therapy in MBC.

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. Jack Hu', is positioned above the printed name.

S. Jack Hu
Vice President for Research

March 2018