

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 “Derivation of endocrine and chemotherapy resistance gene signatures and evaluation of previously developed molecular signatures as prognostic and predictive biomarkers in SWOG 8814” (ORSP #19-PAF05394) in the Department of Radiation Oncology under the direction of Drs. James Rae and Corey Speers. The purpose of this project is to use RNA expression levels from tumors obtained from patients from a previously completed, practice changing phase III randomized trial to develop prognostic and predictive signatures of chemotherapy response in women with estrogen receptor-positive, lymph node-positive breast cancer.

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 \$220,266. 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 Drs. Rae and Speers to use their expertise and University laboratories, as well as other University resources, to: 1) compare currently established primary breast cancer molecular signatures of chemotherapy response in the ER+ and LN+ patient cohort, 2) improve the performance of these signatures, and 3) use this data to train a signature with higher sensitivity and specificity for disease-free survival specifically in estrogen receptor-positive (ER+), lymph node-positive (LN+) patients compared to previously derived molecular signatures designed for the ER+, node-negative (LN-) patient population.

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,



Rebecca Cunningham
Interim Vice President for Research

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