

THE UNIVERSITY OF MICHIGAN
REGENTS COMMUNICATION

ACTION REQUEST

Subject: Subcontract Agreement between the University of Michigan and Mekanistic Therapeutics LLC

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 Judith Leopold and Dr. Christopher Whitehead are employees of the University of Michigan (“University”), and partial owners of Mekanistic Therapeutics LLC. 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:

Judith S. Leopold, PhD, a Research Associate Professor in the Department of Radiology, and Christopher E. Whitehead, PhD, a Chemist Staff Specialist in the Department of Radiology, are partial owners of a for-profit company called Mekanistic Therapeutics LLC (the “Company”). The Company wishes to fund a NIH (prime) STTR Phase II project entitled “STTR Phase II Development of MTX-211 for the Treatment of KRAS Mutant and BRAF Mutant Colorectal Cancer” (ORSP# 17-PAF06153) in the Department of Radiology under the direction of Dr. Leopold. The purpose of this project is to carry out pivotal process development and preclinical studies to optimize clinical trial design.

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 \$537,423. 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. Leopold to use her expertise and University laboratory, as well as other University resources, to improve the clinical outcome of patients diagnosed with metastatic colorectal cancer with activating mutation in KRAS and BRAF.

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 Mekanistic Therapeutics LLC.

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

April 2017