

THE UNIVERSITY OF MICHIGAN  
REGENTS COMMUNICATION

ACTION REQUEST

Subject: Research Agreement between the University of Michigan and Eli Lilly and Company

Action Requested: Authorization to amend an Agreement

Preamble:

A statutory conflict of interest situation was identified by the Office of Research and Sponsored Projects while reviewing the Proposal Approval Form.

This proposed agreement (“Agreement”) falls under the State of Michigan Conflict of Interest Statute because Dr. Marschall Runge is an employee of the University of Michigan (“University”), and a paid member of the Board of Directors of Eli Lilly and Company. 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:

Marschall Runge, MD, PhD, the Executive Vice President for Medical Affairs and Dean of the Medical School, is a paid member of the Board of Directors of the for-profit company called Eli Lilly and Company (the “Company”). The Company wishes to amend a research agreement previously approved by the Regents on March 16, 2017 to include the proposal entitled, “A Phase 2, Multicenter, Randomized, Parallel-arm, Placebo-Controlled Study of LY3074828 in Subjects with Moderate to Severely Active Crohn's Disease Synopsis” (ORSP #19-PAF01569) in the Department of Internal Medicine – Gastroenterology under the direction of Dr. Peter Higgins. The purpose of this amendment is to evaluate safety and determine the clinical activity defined by improvement in Crohn’s disease activity measures and key patient-reported outcomes (PRO) measures. Dr. Runge is not involved in any manner in this research project and was not involved in any manner in the negotiation of the Agreement terms.

Agreement Terms:

The terms of the Amendment conform to University policy. The period of performance for the project is approximately three (3) years. The amount of funding support will be increased by \$3,011 and will not exceed \$241,310. 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 amended Agreement will provide continued support of an effort by Dr. Higgins to use his expertise and Internal Medicine clinic and office space, as well as other University resources, to work collaboratively with the Company to help evaluate safety and determine the clinical activity defined by improvement in Crohn's disease activity measures and key patient-reported outcomes (PRO) measures.

Recommendations:

Dr. Runge has properly disclosed his service to the Company pursuant to the regular conflict of interest process and policies that apply to Executive Officers of the University. The president has put in place a management plan for this conflict which calls for Dr. Runge to recuse himself from any University decisions involving a business relationship with the Company and to inform the president when he is required to do so. 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 amending this Agreement with Eli Lilly and Company.

Respectfully submitted,

A handwritten signature in blue ink, appearing to read 'S. Hu', is written over the typed name.

S. Jack Hu  
Vice President for Research

October 2018