

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 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.

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 fund a project entitled "I6T-MC-AMAG A Phase 2, Multicenter, Randomized, Parallel-Arm, Placebo Controlled Study of LY3074828 in Subjects with Active Crohn's Disease (SERENITY)" (ORSP #17-PAF03941) in the Department of Internal Medicine-Gastroenterology and Hepatology under the direction of Dr. Peter Higgins, MD, to test the hypothesis that treatment with LY3074828 is superior to placebo in the proportion of subjects with endoscopic response at week 12, defined as 50% reduction from baseline in SES-CD score. 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 Agreement conform to University policy. The period of performance for the project is approximately three (3) years. The amount of funding support will not exceed \$238,299. 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 Dr. Peter Higgins to use his expertise and Department of Internal Medicine clinic space, as well as other University resources, to work collaboratively with the Company to focus on providing 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 entering into this Agreement with Eli Lilly and Company.

Respectfully submitted,



S. Jack Hu  
Vice President for Research

March 2017