

THE UNIVERSITY OF MICHIGAN
REGENTS COMMUNICATION

ACTION REQUEST

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

Action Requested: Approval of Amendment to 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 amendment to the agreement (“Amendment”) 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”). In July 2016, the Regents approved a contract agreement between the Company and the University entitled, “A I6T-MC-AMAC: Phase 2, Multicenter, Randomized, Double-Blind, Parallel, Placebo-Controlled Study of LY3074828 in Subjects with Moderate to Severe Ulcerative Colitis” (ORSP # 16-PAF05786) in the Department of Internal Medicine - Gastroenterology under the direction of Peter Higgins, MD, PhD, to test the hypothesis that treatment with LY3074828 is superior to placebo in inducing clinical remission at Week 12 in subjects with moderate to severe ulcerative colitis (UC). Dr. Runge was not involved in any manner in this research project and was not involved in any manner in the negotiation of the Agreement terms. The University will amend the active Agreement with the Company to add additional study visits as described in the amended protocol (ORSP # 17-PAF06532).

Agreement Terms:

The terms of the amended Agreement conform to University policy. The period of performance for the project is extended for an additional two (2) years for an approximate total of four (4) years. The amount of funding support will be increased by \$222,216 and will not exceed \$436,490. 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 continue to support an effort by Dr. Peter Higgins to use his expertise and Internal Medicine clinic space clinic office space, as well as other University resources, to work collaboratively with the Company to focus on providing efficacy data on intravenous (IV) administration of LY3074828 (3 doses versus placebo) in subjects with moderate to severe UC.

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 and this Amendment were 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,



S. Jack Hu
Vice President for Research

July 2017