

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, “A Randomized, Placebo-Controlled, Double-Blind, Sponsor Unblinded, Single Ascending Dose, Phase 1 First in Human Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of Intravenous LY3819253 in Participants Hospitalized for COVID-19 (J2W-MC-PYAA)” (ORSP #20-PAF07965) in the Department of Surgery, General Surgery Division under the direction of Dr. Pauline Park. The purpose of this project is to investigate the safety, tolerability, pharmacokinetics (PK), and pharmacodynamics (PD) of LY3819253 following a single dose of LY3819253 administered to participants hospitalized for COVID-19. 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 one (1) year. The amount of funding support will not exceed \$285,000. 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.

This agreement includes the provision that the University will be entitled to amend or terminate the agreement in the event that Regental approval is not obtained.

Impact of the Agreement:

The Agreement will support an effort by Dr. Park to use her expertise and the Department of Surgery, as well as other University resources, to work collaboratively with the Company to investigate the safety, tolerability, pharmacokinetics (PK), and pharmacodynamics (PD) of LY3819253 following a single dose of LY3819253 administered to participants hospitalized for COVID-19.

Recommendations:

Due to the rapid spread of the novel coronavirus (COVID-19) and time sensitive nature of this agreement to assist in the treatment and mitigation of the spread, the Vice President for Research has reviewed this agreement and her signature on this action request signifies provisional approval for the University to enter into the agreement prior to Regental approval.

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,



Rebecca Cunningham  
Vice President for Research

June 2020