

THE UNIVERSITY OF MICHIGAN
REGENTS COMMUNICATION

ACTION REQUEST

Subject: Amendment to Research Agreement between the University of Michigan and Lycera Corp.

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 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 amendment to the research agreement (“Agreement”) falls under the State of Michigan Conflict of Interest Statute because Professor Anthony Opipari and Dr. David Canter are employees of the University of Michigan (“University”), and partial owners of Lycera Corp. 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:

Dr. Anthony Opipari, an Associate Professor in the Department of Obstetrics and Gynecology, and Dr. David Canter, the Senior Associate Vice President and Executive Director of the North Campus Research Complex, are partial owners of a for-profit company called Lycera Corp. (the “Company”). The Company wishes to continue to fund a project entitled: “A Randomized, Double-blind, Placebo-controlled Parallel Group Study to Assess the Efficacy and Safety of Induction Therapy with LYC-30937-EC in Subjects with Active Ulcerative Colitis/LYC-30937-2001” (ORSP#s 18-PAF01503 and 18-PAF02114) in the Department of Internal Medicine-Gastroenterology under the direction of Dr. Ryan Stidham. The original Agreement was approved by the Regents on July 21, 2016. The purpose of this project is to evaluate the efficacy, safety, and tolerability of LYC-30937-EC compared to placebo in subjects with Ulcerative Colitis (UC).

Agreement Terms:

The terms of the amended Agreement conform to University policy. The period of performance for the project is extended for an additional one (1) year for an approximate total of two (2) years. The amount of funding support will be increased by \$75,151 and will not exceed \$137,682. 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 amended Agreement will continue to support an effort by Dr. Stidham to use his expertise and University resources to assess the efficacy of LYC-30937-EC in inducing remission compared with placebo in subjects with active UC over a treatment duration of eight weeks.

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 amended Agreement with Lycera Corp.

Respectfully submitted,



S. Jack Hu
Vice President for Research

October 2017