THE UNIVERSITY OF MICHIGAN REGENTS COMMUNICATION

ACTION REQUEST

<u>Subject:</u> Sponsored Activity Agreement between the University of Michigan and ONL Therapeutics, Inc.

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 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 sponsored activity agreement ("Agreement") falls under the State of Michigan Conflict of Interest Statute because Professor David Zacks is an employee of the University of Michigan ("University"), and a partial owner and member of the Board of Directors of ONL Therapeutics, Inc. 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. David Zacks, a Professor in the Department of Ophthalmology and Visual Sciences, is the partial owner and member of the Board of Directors of a for-profit company called ONL Therapeutics, Inc. (the "Company"). The Company wishes to fund a sponsored activity entitled "Testing neuroprotective effect of ONL-1204 ocular formulation dose response in mouse retinal ischemia injury model" (ORSP #18-PAF00710) in the Department of Ophthalmology and Visual Sciences under the direction of Dr. Steven Abcouwer. The purpose of this project is to test the efficacy of intravitreal injections of three dosages of the Fas inhibiting peptide ONL1204 on the neurodegenerative (apoptotic) response to retinal ischemia-reperfusion (IR) injury in mice. Dr. Zacks is not involved in this project at the University nor at ONL Therapeutics, Inc.

Agreement Terms:

The terms of the Agreement conform to University policy. The period of performance is approximately three (3) months. The amount of funding support will not exceed \$5,850. Since such agreements 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. Steven Abcouwer to test the efficacy of intravitreal injections of three dosages of the Fas inhibiting peptide ONL1204 on the neurodegenerative (apoptotic) response to retinal ischemia-reperfusion (IR) injury in mice.

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 <u>recommend</u> that the Board of Regents approve the University's entering into this Agreement with ONL Therapeutics, Inc.

Respectfully submitted,

S. Jack Hu Vice President for Research

September 2017