THE UNIVERSITY OF MICHIGAN REGENTS COMMUNICATION

ACTION REQUEST

<u>Subject:</u> Subcontract Agreement between the University of Michigan

and Opsidio, LLC

<u>Action Requested</u>: 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 agreement ("Agreement") falls under the State of Michigan Conflict of Interest Statute because Professors Nicholas Lukacs and Steven Kunkel are employees of the University of Michigan ("University"), and a partial owner of Opsidio, LLC. 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. Nicholas Lukacs, a Professor in the Department of Pathology, and Dr. Steven Kunkel, a Professor in the Department of Pathology and Senior Associate Dean for Research, Medical School, are partial owners of a for-profit company called Opsidio, LLC (the "Company"). The Company wishes to fund a NIH (prime) STTR Phase I project entitled "Therapeutic Mabs for Chronic Kidney Disease" (ORSP #17-PAF06063) in the Department of Pathology under the direction of Dr. Nicholas Lukacs. The purpose of this project is to support the development of a therapy using a monoclonal antibody (Mab) to treat and reverse chronic kidney disease.

Agreement Terms:

The terms of the Agreement conform to University policy. The period of performance is one (1) year. The amount of funding support will not exceed \$133,968. 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.

<u>Impact of the Agreement:</u>

The Agreement will support an effort by Dr. Nicholas Lukacs to use his expertise and University resources to further develop and test this important therapy to treat or reverse chronic kidney disease.

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 Opsidio, LLC.

Respectfully submitted,

S. Jack Hu

Vice President for Research

October 2017