THE UNIVERSITY OF MICHIGAN REGENTS COMMUNICATION

ACTION REQUEST

Subject:

Subcontract Agreement between the University of Michigan

and Opsidio, LLC

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 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 partial owners 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:

Nicholas Lukacs, PhD, the Assistant Dean of Research Faculty and a Professor in the Departments of Research and Pathology, Medical School, and Steven Kunkel, PhD, the Senior Associate Dean for Research, Co-Director of the Division of General Pathology, and a Professor in the Department of Pathology, 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# 16-PAF05930) in the Department of Pathology under the direction of Dr. Lukacs. The purpose of this project is to determine whether monoclonal antibody to SCF inhibits development of chronic kidney disease and determine the correlation of SCF during the progression of chronic kidney disease.

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 \$112,273. 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 Agreement will support an effort by Dr. Lukacs to use his expertise and University laboratory, as well as other University resources to coordinate, direct and supervise research activities in his lab regarding research on animal and database models related to SCF and mast cell biology testing.

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 Agreement with Opsidio, LLC.

Respectfully submitted,

S. Jack Hu

Vice President for Research

April 2016