

THE UNIVERSITY OF MICHIGAN
REGENTS COMMUNICATION

ACTION REQUEST

Subject: Subcontract Agreement between the University of Michigan and Opsidio, 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 agreement (“Agreement”) falls under the State of Michigan Conflict of Interest Statute because Professors Steven Kunkel and Nicholas Lukacs are employees of the University of Michigan (“University”), and partial owners of Opsidio, 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:

Steve Kunkel, PhD, a Professor in the Department of Pathology, the Interim Executive Vice Dean of Research, Interim Chief Scientific Officer, and Senior Associate Dean for Research in the University’s Medical School, and Nicholas Lukacs, PhD, a Professor in the Department of Pathology, are partial owners of a for-profit company called Opsidio, Inc. (the “Company”). The Company wishes to fund a NIH (prime) STTR Phase II project entitled “Therapeutic Mabs for Chronic Kidney Disease” (ORSP #19-PAF06178) in the Department of Pathology under the direction of Dr. Lukacs. The purpose of this project is to validate that a newly humanized monoclonal antibody (“mAb”) to SCF248 in animal models of CKD can arrest and possibly reverse the fibrosis that is the cause of renal failure.

Agreement Terms:

The terms of the Agreement conform to University policy. The period of performance for the project is approximately two (2) years. The amount of funding support will not exceed \$493,810. 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.

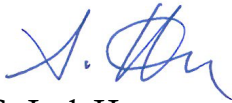
Impact of the Agreement:

The Agreement will support an effort by Dr. Lukacs to use his expertise and University laboratories, as well as other University resources, to validate that a newly humanized monoclonal antibody (“mAb”) to SCF248 in animal models of CKD can arrest, and possibly reverse the fibrosis that is the cause of renal failure.

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, Inc.

Respectfully submitted,



S. Jack Hu
Vice President for Research

May 2019