

THE UNIVERSITY OF MICHIGAN
REGENTS COMMUNICATION

ACTION REQUEST

Subject: Subcontract Agreement between the University of Michigan and Therapeutic Systems Research Laboratories, 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 UMOR Conflict of Interest Review Committee. A plan for management of the possible risks associated with the conflict of interest was then developed and approved by the Committee and agreed to by the parties involved.

This proposed agreement (“Agreement”) falls under the State of Michigan Conflict of Interest Statute because Professor Gordon Amidon is an employee of the University of Michigan (“University”) and a partial owner of Therapeutics System Research Laboratories, Inc. (“TSRL”), and because Professor Gregory Amidon is an employee of the University and a paid member of the Board of Directors of TSRL. 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. Gordon Amidon, a Professor in the Department of Pharmaceutical Sciences, is the partial owner of a for-profit company called TRSL, and Dr. Gregory Amidon, a Research Professor in the Department of Pharmaceutical Sciences, is a paid member of the Board of Directors of TSRL (the “Company”). The Company wishes to fund a NIH (prime) SBIR Phase I project entitled: “A novel combination therapy to targeting biofilms in diabetic foot ulcer infections” (ORSP# 19-PAF03761) in the Department of Internal Medicine, under the direction of Dr. Keith Kaye. The purpose of this project is to demonstrate that the combination of triclosan and tobramycin is effective against biofilm-forming wound pathogens and displays pharmacokinetic (PK) properties suitable for topical administration with safety characteristics to justify further development towards an Investigational New Drug (IND) application.

Agreement Terms:

The terms of the Agreement conform to University policy. The period of performance for the project is approximately four (4) years. The amount of funding support will not exceed \$84,407. Since research projects are often amended, this agreement will include 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. Kaye to use his expertise and University laboratories, as well as other University resources, to function as the clinical expert team member on the topical tobramycin/triclosan combination product development team, and provide advice on the clinical development plans and trial designs.

Recommendations:

This matter has been reviewed and approved by the UMOR Conflict of Interest Review Committee. 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 Therapeutic Systems Research Laboratories, Inc.

Respectfully submitted,

A handwritten signature in blue ink, appearing to read 'S. Jack Hu', is positioned above the printed name.

S. Jack Hu
Vice President for Research

February 2019