

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 Therapeutic Systems Research Laboratories, Inc. ("TSRL"), and because Professor Gregory Amidon is an employee of the University and has a leadership role in 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 TSRL, and Dr. Gregory Amidon, a Research Professor in the Department of Pharmaceutical Sciences and Program Director of Pharmaceutical Engineering, has a leadership role with TSRL (the "Company"). The Company wishes to fund a NIH (prime) SBIR Phase I project titled: "A Distraction Osteogenesis-Enabling Therapeutic Solution for Mandibular Craniofacial Reconstructive Surgery" (ORSP# 17-PAF00989) in the Department of Plastic Surgery under the direction of Dr. Steven Buchman. The purpose of this project is to develop an oral formulation of Amifostine to minimize the impact of radiation injury using a more feasible method of administration.

Agreement Terms:

The terms of the Agreement conform to University policy. The period of performance for the project is approximately three (3) years. The amount of funding support will not exceed \$574,906. 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. Steven Buchman to use his expertise and University laboratory, as well as other University resources, to develop new and improved treatment modalities of Amifostine.

## 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,



S. Jack Hu  
Vice President for Research

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