

ACTION REQUEST

Subject: Subcontract Agreement between the University of Michigan and NOTA Laboratories 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 and 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 Board and Committee and agreed to by the parties involved.

This proposed agreement ("Agreement") falls under the State of Michigan Conflict of Interest Statute because Professors Mark E. Meyerhoff, Mark A. Zacharek, Marc B. Hershenson, and Umadevi S. Sajjan are all employees of the University of Michigan ("University"), and partial owners of NOTA Laboratories 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:

Mark E. Meyerhoff, PhD, a Professor in the Department of Chemistry, Mark A. Zacharek, MD, an Associate Professor in the Department of Otolaryngology, Marc B. Hershenson, MD, a Professor in the Department of Pediatrics and Communicable Diseases, and Umadevi S. Sajjan, PhD, a Research Assistant Professor in the Department of Pediatrics and Communicable Diseases, are partial owners of a for-profit company called NOTA Laboratories LLC (the "Company"). The Company wishes to fund a National Institutes of Health (prime) STTR Phase I project entitled "Photo-Release of Nitric Oxide for In-Home Inhalation Therapy of Chronic Respiratory Infections" (ORSP# 16-PAF00871) in the Department of Chemistry under the direction of Drs. Mark Meyerhoff and Marc Hershenson. The purpose of this project is to lead the translation of a new in-home nitric oxide (NO) inhalation (iNO) technology to treat patients with COPD, CRS, and CF, using NO to prevent or treat sinus and other respiratory tract infections.

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 \$122,000. 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 Drs. Meyerhoff and Hershenson to use their expertise and University laboratory, as well as other University resources to lead the translation of a new in-home nitric oxide (NO) inhalation (iNO) technology to treat patients with COPD, CRS, and CF.

Recommendations:

This matter has been reviewed and approved by the Medical School Conflict of Interest Board and 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 NOTA Laboratories LLC.

Respectfully submitted,



S. Jack Hu
Interim Vice President for Research

October 2015