

THE UNIVERSITY OF MICHIGAN
REGENTS COMMUNICATION

ACTION REQUEST

Subject: Subcontract Agreement between the University of Michigan and Arbor Medical Innovations, 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 this 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 Steven Harte and Grant Kruger are employees of the University of Michigan ("University"), and partial owners of Arbor Medical Innovations, 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:

Steven Harte, PhD, an Assistant Research Scientist in the Departments of Internal Medicine-Rheumatology and Anesthesiology, Medical School, and Grant Kruger, PhD, an Assistant Research Scientist in the Department of Mechanical Engineering, College of Engineering, and Research Investigator in the Department of Anesthesiology, Medical School, are partial owners of a for-profit company called Arbor Medical Innovations, LLC (the "Company"). The Company wishes to fund an NIH (prime) SBIR Phase I project entitled "Continuous Volume Responsiveness Sensor to Optimize the Fluid Resuscitation of Sepsis Patients" (ORSP# 17-PAF04021) in the Department of Emergency Medicine under the direction of Dr. Ross Kessler. The purpose of this project is to develop a fully-autonomous, ultrasound-based wearable sensor to noninvasively and continuously monitor geometric changes in the internal jugular vein in order to track volume responsiveness in septic patients.

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 \$61,408. 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. Kessler 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 human subjects questionnaires, protocols, assessing prototype results, modify testing system and, support technical analysis of data processing results.

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 Arbor Medical Innovations, LLC.

Respectfully submitted,



S. Jack Hu
Vice President for Research

February 2017