

THE UNIVERSITY OF MICHIGAN  
REGENTS COMMUNICATION

ACTION REQUEST

Subject: Subcontract Agreement between the University of Michigan and Blaze Medical Devices, 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 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 Dr. Kenneth Alfano is an employee of the University of Michigan ("University"), and a partial owner of Blaze Medical Devices, 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:

Dr. Kenneth Alfano, a Lecturer IV in the College of Engineering Undergraduate Education, is the partial owner of a for-profit company called Blaze Medical Devices, LLC (the "Company"). The Company wishes to fund a FDA (prime) SBIR Phase I project entitled: "RBC Mechanical Fragility and VAD Blood Damage" (ORSP #15-PAF00454) in the Department of Cardiac Surgery under the direction of Dr. Francis Pagani, Professor of Cardiac Surgery in the Medical School. The purpose of this project is for the collection and tabulation of subject-related medical history Data collection, analysis and interpretation.

Agreement Terms:

The terms of the Agreement conform to University policy. The period of performance for the project is approximately six (6) months. The amount of funding support will not exceed \$48,704. 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. Pagani to use his expertise and University laboratory, as well as other University resources for the collection and tabulation of subject-related medical history Data collection, analysis and interpretation.

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 Blaze Medical Devices, LLC.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'S. Jack Hu', written in a cursive style.

S. Jack Hu  
Interim Vice President for Research

December 2015