

THE UNIVERSITY OF MICHIGAN
REGENTS COMMUNICATION

ACTION REQUEST

Subject: Subcontract Agreement between the University of Michigan and Amplitude Vascular Systems, Inc. (formerly known as Calcium Solutions, 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 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 the Committee and agreed to by the parties involved.

This proposed subcontract agreement (“Agreement”) falls under the State of Michigan Conflict of Interest Statute because Professors Hitinder Gurm and Albert Shih are employees of the University of Michigan (“University”), and partial owners of Amplitude Vascular Systems, Inc. (formerly known as Calcium Solutions, Inc.). 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. Hitinder Gurm, a Professor in the Department of Internal Medicine – Cardiology, and Dr. Albert Shih, a Professor in the Department of Mechanical Engineering, are partial owners of a for-profit company called Amplitude Vascular Systems, Inc. (the “Company”). The Company wishes to fund a National Institutes of Health (prime) STTR Phase I project entitled, “STTR Phase I: Pulse: Harmonic Balloon Angioplasty Device for Treatment of Peripheral Artery Calcification - R41/42 subK resub” (ORSP #21-PAF01013) in the Department of Internal Medicine – Cardiology under the direction of Dr. Gurm. The purpose of this project is to perform safety and efficacy testing of the Company’s Pulse device.

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 \$106,160. 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. Gurm to use his expertise and University laboratory, as well as other University resources, to perform safety and efficacy testing of the Company's Pulse device.

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 Amplitude Vascular Systems, Inc.

Respectfully submitted,



Rebecca Cunningham
Vice President for Research

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