

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 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 subcontract agreement (“Agreement”) falls under the State of Michigan Conflict of Interest Statute because Drs. 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:

Dr. Steven Harte, an Associate Research Scientist in the Department of Anesthesiology, and Dr. Grant Kruger, an Associate Research Scientist in the Department of Mechanical Engineering, are partial owners of a for-profit company called Arbor Medical Innovations, LLC (the “Company”). The Company wishes to fund a National Institutes of Health (prime) SBIR Phase I/II project entitled, “Actigraphy Enhanced Pain Management” (ORSP #20-PAF08795) in the Department of Anesthesiology under the direction of Dr. Harte. The purpose of this project is to develop the first waterproof, recyclable, “invisible” actigraphy wearable that does not present any technical burden to the patient and that can collect accurate daily activity and sleep data outside the pain clinic and transfer these data to a central processing facility.

Agreement Terms:

The terms of the Agreement conform to University policy. The period of performance for the project is approximately five (5) years. The amount of funding support will not exceed \$750,549. 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. Harte to use his expertise and University laboratory, as well as other University resources, to develop human subjects protocols, obtain regulatory approvals, collect human subjects data, manage study databases, analyze and interpret data for dissemination and product improvement.

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,



Rebecca Cunningham
Vice President for Research

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