THE UNIVERSITY OF MICHIGAN REGENTS COMMUNICATION

ACTION REQUEST

Subject:

Research Agreement between the University of Michigan and

Brio Device LLC

Action Requested:

Authorization to enter into Agreement

Preamble:

A statutory conflict of interest situation was identified by the Office for Research and Sponsored Projects while reviewing the Proposal Approval Form which then triggered a review by the Medical School Conflict of Interest Board. The Board concluded that the proposed agreement presents minimal risk and approved it with disclosure as sufficient management.

This proposed agreement ("Agreement") falls under the State of Michigan Conflict of Interest Statute because Drs. Laura L. McCormick, Sabina Siddiqui, and Douglas Mullen, are all employees of the University of Michigan ("University") and partial owners of Brio Device LLC ("Brio"). 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. Laura McCormick, a temporary employee in the Medical Innovation Center, Dr. Sabina Siddiqui, a Clinical Lecturer at the Medical School, and chief medical officer of Brio, and Dr. Douglas Mullen, an Entrepreneur in Residence at MNIMBS, are all partial owners of a for-profit company called Brio (the "Company"). The Company was formed recently to further develop and commercialize airway management devices for emergency care. The Company wishes to support a research project at the University of Michigan with funding from the National Institutes of Health to develop the images and control algorithms for an endotracheal intubation device to recognize anatomical structures to guide intubation, with a view toward to developing a guided control system that would help doctors perform emergency intubation safely (ORSP #12-PAF06208).

Agreement Terms:

The terms of the Agreement will conform to University policy. Dr. Honglak Lee, Associate Professor of Electrical Engineering and Computer Science, College of Engineering, together with Dr. David Healy, Assistant Professor and Director, Head and Neck Anesthesiology, Department of Anesthesiology will co-direct the project over an eight (8) month period and the amount of funding support is \$69,141. The Company seeks to enter into a Research Agreement with the University with the purpose of enabling the Company to develop hardware components and datasets to develop the images and control algorithms for an endotracheal intubation device to recognize anatomical structures to guide intubation, and eventually to develop a guided control system that would help doctors perform emergency intubation safely.

Since research projects are often amended, this agreement will include provisions for changes in the time, amount, and scope of the project. In the case of such proposed amendment, University procedures for approval of the terms and conditions governing the amended work 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. Lee and Healy to use their expertise and University resources to facilitate the generation and evaluation of improved intubation technique and devices.

Recommendation:

This matter has been reviewed and approved by the Medical School Conflict of Interest Board. In light of the disclosure made in this document and our finding that the Agreement will be negotiated in conformance with standard University practices, I <u>recommend</u> that the Board of Regents approve of the University's entering into this Agreement with Brio Device LLC.

Respectfully submitted,

Stephen R. Forrest

Vice President for Research

April 2013