

THE UNIVERSITY OF MICHIGAN
REGENTS COMMUNICATION

ACTION REQUEST

Subject: Subcontract Agreement between the University of Michigan and New Vital Signs, 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. A plan for management of the possible risks associated with the conflict of interest was then developed and approved by the Board and agreed to by the parties involved.

This proposed agreement (“Agreement”) falls under the State of Michigan Conflict of Interest Statute because Professor Kevin Ward is an employee of the University of Michigan (“University”), and a partial owner of New Vital Signs, 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:

Kevin Ward, MD, a Professor in the Department of Emergency Medicine, is the partial owner of a for-profit company called New Vital Signs, Inc. (the “Company”). The Company wishes to fund a NIH (prime) sponsored project entitled, “Dynamic Respiratory Impedance Volume Evaluation (DRIVE) for Sepsis (Ward/Tiba),” (ORSP #19-PAF02230) in the Department of Emergency Medicine under the direction of Dr. Kevin Ward. The purpose of this project is to allow Dr. Ward to further develop a novel limb bioimpedance monitor technique to assess volume status 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 \$350,170. 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. Ward to use his expertise and University laboratory, as well as other university resources, to examine dialysis patients before and after dialysis to verify that the technique will be an ideal, non-invasive, highly-feasible surrogate for real-time monitoring and assessment of intravascular volume status for patients with sepsis.

Recommendations:

This matter has been reviewed and approved by the Medical School Conflict of Interest Board. 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 New Vital Signs, Inc.

Respectfully submitted,

A handwritten signature in blue ink, appearing to read 'S. Hu', is positioned above the printed name.

S. Jack Hu
Vice President for Research

December 2018