# THE UNIVERSITY OF MICHIGAN REGENTS COMMUNICATION

#### ACTION REQUEST

Subject: Subcontract Agreement between the University of Michigan and

Integrated Sensing Systems, 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 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 Professors Khalil Najafi and Kensall D. Wise are employees of the University of Michigan ("University"), and partial owners of Integrated Sensing Systems, 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. Khalil Najafi, a Professor in the Department of Electrical Engineering and Computer Science – Electrical and Computer Engineering (EECS – ECE) Division, and Dr. Kensall D. Wise, a Professor Emeritus in the Department of EECS – ECE Division, are the partial owners of a for-profit company called Integrated Sensing Systems, Inc. (the "Company"). The Company wishes to fund a NIH (prime) SBIR Phase II project entitled "Implantable Intra-Cardiac Pressor Sensor Applications in Patients Receiving Durable Left Ventricular Assist Device Therapy" (ORSP #18-PAF00791) in the Department of Cardiac Surgery under the direction of Dr. Francis Pagani. The purpose of this project is to use Integrated Sensing Systems, Inc. developed novel sensor technology to: 1) facilitate diagnosis and/or mitigate the hemodynamic derangements associated with left ventricular assist device (LVAD) complications; and 2) identify strategies to improve LVAD designs to enhance autoregulation of pump output to more appropriately respond to changes in cardiac loading conditions of patients to improve the overall patient outcomes of LVAD therapy.

## Agreement Terms:

The terms of the Agreement conform to University policy. The period of performance for the project is approximately two (2) years. The amount of funding support will not exceed \$1,359,575. 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.

# <u>Impact of the Agreement:</u>

The Agreement will support an effort by Dr. Pagani to use his expertise and University laboratories to perform studies of preclinical candidate compounds for use in target pull-down.

## 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 <u>recommend</u> that the Board of Regents approve the University's entering into this Agreement with Integrated Sensing Systems, Inc.

Respectfully submitted,

S. Jack Hu

Vice President for Research

February 2018