THE UNIVERSITY OF MICHIGAN REGENTS COMMUNICATION

Approved by the Regents February 19, 2015

ACTION REQUEST

Subject:

Subcontract Agreement between the University of Michigan

and STEL Technologies 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 the UMOR Conflict of Interest Review Committee. A plan for management of the possible risks associated with any conflict of interest was developed and approved by the Board and Committee and agreed to by the parties involved.

The proposed agreement ("Agreement") falls under the State of Michigan Conflict of Interest Statute because Professors Ellen Arruda, Lisa Larkin, Edward Wojtys, and Dr. Michael Smietana are all employees of the University of Michigan ("University") and partial owners of STEL Technologies 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:

Ellen Arruda, Ph.D., a Professor of Mechanical Engineering and Macromolecular Science and Engineering in the College of Engineering, Lisa Larkin, Ph.D., an Associate Professor of Molecular and Integrative Physiology and a Research Associate Professor of Gerontology in the Medical School, and an Associate Professor of Biomedical Engineering in the College of Engineering, Edward Wojtys, M.D., a Professor of Orthopedic Surgery, and Michael Smietana, Ph.D., a Research Fellow in the Center for Entrepreneurship in the College of Engineering, are the partial owners of a for-profit company called STEL Technologies LLC (the "Company"). The Company wishes to fund an NSF (prime) STTR Phase I project entitled: "A Closed System Bioreactor for Automating Tissue Engineered ACL Production." (ORSP# 14-PAF06786) in the Department of Mechanical Engineering under the direction of Dr. Arruda, with Dr. Larkin acting as a Participating Investigator through the Department of Molecular & Integrative Physiology. The purpose of this project is to support Drs. Arruda and Larkin, and the Company in converting an open system ACL implants manufacturing process to a closed system process.

Agreement Terms:

The terms of the Agreement will conform to University policy. The period of performance for the project is approximately twelve (12) months. The amount of funding support from the Company will not exceed \$79,301. Since research projects are often amended, this agreement includes provisions for changes in time, amount,

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 Drs. Arruda and Larkin to use their expertise and University laboratories, as well as other University resources to translate their engineered ligament fabrication methodologies that they use in sheep to a cell line and methodologies suitable for human use, which has the potential to reduce biocompatibility issues (rejection) associated with current treatment options.

Recommendation:

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 the disclosure and our findings that the Agreement was 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 STEL Technologies LLC.

Respectfully submitted,

S. Jack Hu

Interim Vice President for Research

February 2015