

ACTION REQUEST

Subject: Subcontract Agreement between the University of Michigan and ProDevice Medical Supplies and Equipment, 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 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 Professor Albert Shih is an employee of the University of Michigan ("University"), and a partial owner of ProDevice Medical Supplies and Equipment, LLC ("ProDevice"). 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. Albert Shih, a Professor in Mechanical Engineering and Biomedical Engineering in the College of Engineering, is a partial owner of a for-profit company called ProDevice (the "Company"). The Company wishes to fund a NIH (prime) STTR Phase I project entitled: "Accurate Prostate Cancer Diagnosis for Active Surveillance Patients Using a Novel Saturation Biopsy Needle System," (ORSP# 13-PAF05449) in the Urology Department under the direction of Dr. Montgomery. The purpose of this project is to develop a high-yield core needle biopsy device to improve the accuracy in prostate cancer diagnosis. Dr. Shih has no role on this project as a representative of the University or ProDevice.

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 \$77,046. 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 Dr. Montgomery to use his expertise and University laboratory, as well as other University resources to advance their concepts and seek potential licensing agreement.

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 recommend that the Board of Regents approve the University's entering into this Agreement with ProDevice Medical Supplies and Equipment, LLC.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'S. Hu', written in a cursive style.

S. Jack Hu
Interim Vice President for Research

September 2014