

ACTION REQUEST

Subject: Amendment to Master Agreement between the University of Michigan and HistoSonics, Inc.

Action Requested: Approval of Amendment to Master Agreement

Preamble:

A statutory conflict of interest situation was identified by the Office of Research and Sponsored Projects while reviewing a Proposal Approval Form that then triggered a review by the UMOR Conflict of Interest Review Committee and the Medical School Conflict of Interest Board. A plan for management of the possible risks associated with the conflict of interest was then developed by the Committee and Board and agreed to by the parties involved in this plan.

This proposed amendment to the master agreement (“Amendment”) falls under the State of Michigan Conflict of Interest Statute because Professors Charles Cain, Jeffrey Brian Fowlkes, William Roberts, Zhen Xu, and Dr. Timothy Hall are all employees of the University of Michigan (“University”) and partial owners of HistoSonics, 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. Cain, a Professor in the Department of Biomedical Engineering and Electrical Engineering and Computer Science – ECE Division; Dr. Fowlkes, a Professor in the Departments of Radiology and Biomedical Engineering, and the Associate Vice President for Research, Health Sciences in the Office of the Vice President for Research; Dr. Roberts, an Associate Professor in the Departments of Urology and Biomedical Engineering; Dr. Xu, an Associate Professor in the Departments of Biomedical Engineering and Pediatrics and Communicable Diseases; and Dr. Hall, an Assistant Research Scientist and Adjunct Lecturer in the Department of Biomedical Engineering, are partial owners of a for-profit company, HistoSonics, Inc. (the “Company”).

The Company was formed to commercialize histotripsy technologies in a variety of medical applications from the University as disclosed in a previous Regental Action Request. The original Master Agreement was approved at a Regents’ meeting on March 18, 2010. The Company wishes to continue supporting research projects at the University and desires to use facilities of the University for projects related to research and development of these technologies. The roles of Drs. Cain, Fowlkes, Roberts, Xu, and Hall will be described in each project statement for each project and shall be subject to an approved conflict of interest management plan.

Agreement Terms:

The University will amend the active Agreement with the company that will cover standard procedures for performance of projects as well as provisions implementing University and federal policies related to intellectual property and publication. The amendment will extend the end date of the Agreement to June 30, 2020, a period of performance extension of an additional five (5) years. The amount of funding will be increased to an amount not to exceed \$5,000,000. The University will use standard sponsored project accounting procedures to determine the cost of each project under this Agreement. Budgets will be reviewed and approved by authorized representatives of the applicable department(s) and school(s)/college(s) where projects will be performed. The Agreement will allow the University and the Company to specify projects that the University will conduct under the terms of the Agreement. Since sponsored projects are often amended, the Agreement will include provisions for changes in the time, amount, and scope of each supported project. University procedures for approval of each project will be followed and additional conflict of interest review will be done on a project-by-project basis.

Impact of the Agreement

The Agreement amendment will facilitate research and testing that will assist the University in further developing and enabling commercialization of histotripsy technologies in a variety of medical applications. It also provides for ongoing support and collaboration between the University and a University of Michigan start-up company.

Recommendations:

This matter has been reviewed and approved by the UMOR Conflict of Interest Review Committee and the Medical School Conflict of Interest Board and a plan will be developed to manage the potential conflict of interest risks associated with each project that will be implemented under the terms of the Master Agreement prior to the University's approval of any individual project. In light of this disclosure and our finding that the Agreement amendment was negotiated in conformance with standard University practices, I recommend that the Board of Regents approve the University entering into this Agreement with HistoSonics, Inc.

Respectfully submitted,



S. Jack Hu
Interim Vice President for Research

June 2015