THE UNIVERSITY OF MICHIGAN

REGENTS COMMUNICATION

ACTION REQUEST

Subject:

Amendment to License Agreement between the University of Michigan and HistoSonics, LLC

Action Requested:

Approval of Amendment

Preamble:

A statutory conflict of interest situation was identified by the Office of Technology Transfer while reviewing the technology transfer agreement. This then triggered a review by the OVPR Conflict of Interest Committee. A plan for management of the possible risks associated with the conflict of interest was then developed and approved by this Committee and agreed to by the parties involved.

This proposed amendment to the license agreement ("Agreement") falls under the State of Michigan Conflict of Interest Statute because Professors Charles Cain, Brian Fowlke, William Roberts and Drs. Zhen Xu and Timothy Hall, are all employees of the University of Michigan ("University") and partial owners of HistoSonics, LLC. The law permits such an Agreement provided it is disclosed to the executive officers and approved in advance by a 2/3 vote of the Regents of the University of Michigan.

Background:

Dr. Charles Cain, Professor in Biomedical Engineering, Dr. Brian Fowlke, Associate Professor of Radiology, Dr. William Roberts, Assistant Professor of Urology, Dr. Zhen Xu, Assistant Research Scientist in Biomedical Engineering, and Timothy L. Hall, Research Fellow of Urology are partial owners of a for-profit company called HistoSonics, LLC ("Company"). The Company recently obtained a license to a variety of histotripsy technologies in a number of medical applications and desires to add to the license Michigan's rights in the following jointly invented and owned technology:

UM OTT File No. 4611, entitled: "Patient Interface Between an Ultrasound Therapy Transducer and the Perineal Window" (Cain, Roberts, Hall, Fowlke and Xu)

Parties to the Agreement:

The Regents of the University of Michigan and HistoSonics, LLC.

Agreement Terms:

License terms include giving the Company an exclusive license with the right to grant sublicenses in the field of use of medical devices. The Company will reimburse patent costs, pay milestone and annual minimums and royalties on sales. The University will retain ownership of the licensed technology and may continue to further develop it and use it internally. No use of University services or facilities, nor any assignment of

University employees, is obligated or contemplated under the agreement. Standard disclaimers of warrantees and indemnification apply, and the contract may be amended by consent of the parties. University procedures for approval of these changes will be followed and additional conflict of interest review will be done as appropriate.

Pecuniary Interest:

The pecuniary interests of Drs. Cain, Fowlke, Roberts, Xu and Hall arise from their ownership interest in HistoSonics, LLC.

Net Effect:

The Office of Technology Transfer has negotiated and finalized the terms of an amendment to the existing license agreement for patents related to UM OTT File No. 4611.

Recommendations:

This matter has been reviewed and approved by the OVPR 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 Amendment to License Agreement between the University and HistoSonics, LLC.

Respectfully Submitted,

Stephen R. Forrest

Vice President for Research

November 2010