

THE UNIVERSITY OF MICHIGAN

Approved by the Regents
September 15, 2011

REGENTS COMMUNICATION

ACTION REQUEST

Subject: Amendment to Master Agreement between the University of Michigan and Michigan Critical Care Consultants, Inc.

Action Requested: Approval of Amendment to Master Agreement

Preamble:

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

This proposed amendment to the Master agreement ("Agreement") falls under the State of Michigan Conflict of Interest Statute because Dr. Bartlett is both an employee of the University of Michigan ("University") and a part owner and member of the Scientific Advisory Board of Michigan Critical Care Consultants, Inc. 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.

Background:

Dr. Bartlett, a Professor of Surgery in the Medical School, is a part owner and member of the Scientific Advisory Board of Michigan Critical Care Consultants, Inc. (the "Company"). The Company wishes to have the University participate in various projects that the Company will support independently, or from grants from federal agencies related to artificial organ technology. An Action Request was approved in November 2007 with an authorized funding level not to exceed \$500,000 over a five-year period. That funding level has been achieved and an Amendment is necessary to enable additional research efforts. The role of Dr. Bartlett in each project will be described in a project statement and a conflict of interest management plan.

Amendment Terms:

The University will amend the Agreement with the Company that covers standard procedures for performance of projects as well as provisions implementing University and federal policies related to intellectual property and publication. The Amendment will increase the total authorization over the initial five-year period not to exceed \$2,000,000. The University will use standard sponsored project accounting procedures to determine the cost of each project. Budgets will be reviewed and

approved by authorized representatives of each department and school/college where projects are to be performed. The Amendment will allow the University and the Company to continue to specify projects that the University will conduct under the terms of the Master Agreement. Since research projects are often amended, the Master Agreement includes provisions for changes in 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 Amendment will enable the University to participate in important research efforts to explore and further develop the technology related to artificial organ development and transplant. It also provides for ongoing support and collaboration between the Medical School and a University start-up company.

Recommendation:

These matters will be reviewed by 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 acceptance of any individual project. In light of the disclosure made in this document and our finding that the Master Agreement is negotiated in conformance with standard University practices, I recommend that the Board of Regents approve of the University entering into this Master Amendment with Michigan Critical Care Consultants, Inc.

Respectfully submitted,



Stephen R Forrest
Vice President for Research

September 2011