

THE UNIVERSITY OF MICHIGAN
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 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. A plan for management of the possible risks associated with the conflict of interest was then developed by the Board and agreed to by the parties involved.

This proposed amendment to the master agreement ("Agreement") falls under the State of Michigan Conflict of Interest Statute because Dr. Robert Bartlett is both an employee of the University of Michigan ("University") and partial owner of Michigan Critical Care Consultants, Inc. ("MC3, 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. Bartlett, a Professor Emeritus of Surgery, is a partial owner of a for-profit company called MC3, Inc. (the "Company"). The Company was formed to commercialize artificial organ development and transplant technology from the University as disclosed in previous Regental Action Requests. The Company has had various previously approved subcontracts to and from the University under federal grants. 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 role of Dr. Bartlett will be described in each project statement for each project and shall be subject to an approved conflict of interest management plan.

Amendment Terms:

The University will amend the 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 to extend the end date of the Agreement to December 31, 2017 and increase the amount of total funding over the term of the Agreement to an amount not to exceed \$3,000,000. 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 the applicable department(s) and school(s)/college(s) where projects will be performed. This Amendment will allow the University and the Company to specify projects that the University will conduct under the terms of the Agreement. Since research projects are often

amended, the Agreement will include 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 Agreement amendment will enable research to be performed in a timely manner to explore and further develop the technology related to artificial organ development and transplant. It also provides for ongoing support and collaboration between the University and a University start-up company.

Recommendation:

These matters will be reviewed and approved 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 and our finding that the Agreement amendment will be negotiated in conformance with standard University practices, I recommend that the Board of Regents approve of the University entering into this Agreement with MC3, Inc.

Respectfully submitted,



S. Jack Hu
Interim Vice President for Research

June 2014