#### THE UNIVERSITY OF MICHIGAN

Approved by the Regents April 16, 2009

REGENTS COMMUNICATION

# **ACTION REQUEST**

Subject:

Master Agreement between the University of Michigan and

Accord Biomaterials, LLC

Action Requested: Authorization to enter into 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 will be developed by the Board and agreed to by the parties involved.

This proposed Master Agreement falls under the State of Michigan Conflict of Interest Statute because Dr. Robert Bartlett is both an active Professor Emeritus of the University of Michigan and a Co-Founder, of Michigan Critical Care Consultants ("MC3"). Accord Biomaterials, LLC ("Accord") is a partially owned subsidiary of MC3. 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. Robert Bartlett is both an active Professor Emeritus of Surgery in the Medical School, and a Co-Founder of Michigan Critical Care Consultants. Dr. Bartlett also serves as a Scientific Advisory Board Member and unpaid Consultant to MC3. MC3 develops and commercializes early-stage medical device technologies that expand the possibilities of medical treatments. Accord is a venture-backed spin-off from MC3 and remains a partially owned subsidiary of MC3. Accord's core technology revolves around nitric oxide releasing and nitric oxide generating materials and coatings for medical devices. Dr. Bartlett was the inventor of these technologies that are owned by the University. Accord licenses these technologies from the University and the University is entitled to royalties from this license (the license was separately approved by the Board of Regents on February 19, 2009). Accord wishes to have the University participate in various projects that Accord will support independently, from grants from federal agencies, or internally from Accord itself. The University, in its sole discretion, may also wish to have Accord participate in various projects that the

University may support independently, from grants from federal agencies or other sources. The role of Dr. Bartlett with respect to MC3 has been disclosed and under management by the Medical School Conflict of Interest Board since November 24, 2003. The role of Dr. Bartlett in each project under the Master Agreement will be described in a project statement and a conflict of interest management plan.

# Agreement Terms:

The University will enter into a Master Agreement with Accord 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 Master Agreement will cover an initial five-year period with a total authorization not to exceed \$500,000. The University will use standard sponsored project accounting procedures to determine the cost of each project. Accord will use substantially similar and compatible 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 Master Agreement will allow the University and Accord to specify projects that the University will conduct under the terms of the Master Agreement, or that Accord will conduct under 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 review by the Medical School Conflict of Interest Board will be done on a project-by-project basis.

# Impact of the Agreement:

The Master Agreement will enable research to be performed in a timely manner and to explore and further develop better materials and coatings for medical devices to the benefit of patient care.

### 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 was negotiated in conformance with standard University practices; I <u>recommend</u> that the Board of Regents approve of the University entering into this Master Agreement with Accord Biomaterials, LLC.

Respectfully submitted,

Stephen R. Forrest

Vice President for Research

April 2009