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REGENTS COMMUNICATION	i	ACTIONPROVED BY THE REGENTS
ACTION REQUEST	NOTE:	APR 2 1 2005
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Subject:

Subcontract Agreement between the University of Michigan

and Michigan Critical Care Consultants, Inc.

Action Requested: Authorization to enter into Agreement

Preamble:

A statutory conflict of interest situation was identified by DRDA while reviewing the Proposal Approval Form that then triggered a review by the Medical School's 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 agreement (Agreement) falls under the State of Michigan Conflict of Interest Statute because Dr. Robert Bartlett is both an employee of the University and a part owner of Michigan Critical Care Consultants ("Company") a for-profit company. 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. Robert Bartlett, Professor of Surgery in the Medical School, is a part owner in a small business called Michigan Critical Care Consultants, Inc. (MC3). MC3 has had various previously approved agreements with the University including subcontracts to and from the University under federal grants. MC3 now wishes to subcontract with the University for research that is supported by a grant from the National Institutes of Health (NIH). The Principal Investigator for the project at the University is Dr. Keith Cook, a Research Investigator in Biomedical Engineering and Surgery, who has no proprietary or other interest in MC3. Dr. Bartlett will serve as a co-investigator on the project in his University capacity.

Nature of the Agreement:

MC3 wishes to subcontract a portion of its Phase II SBIR titled "Total Artificial Lung Clinical Studies" to the University to assist with the development of an artificial lung.

Agreement Terms:

Under the project a total subcontract of \$467,532 is anticipated to cover the period November 1, 2004, through October 31, 2007. The University's standard subcontract provisions will apply. Since research agreements are often amended, the subcontract includes provisions for changes in time, amount, and scope of the research.

University procedures for approval of these changes will be followed and additional review by the Medical School Conflict of Interest Board will be done as appropriate.

Impact of the Agreement:

The subcontract with MC3 will allow the University of Michigan to participate with the development of a Total Artificial Lung for Preclinical studies and assist MC3 in meeting the goals and objectives originally submitted to NIH.

Recommendation:

This project has been reviewed and approved by the Medical School's Conflict of Interest Board and by the Medical School. In light of the disclosure made in this document and our finding that the agreement was negotiated in conformance with standard University practices, I <u>recommend</u> that the Board of Regents approve of the University's entering into this Agreement with Michigan Critical Care Consultants, Inc.

Respectfully submitted,

Pawwaz T. Ulaby

Vice President for Research

April 2005