THE UNIVERSITY OF MICHIGAN
REGENTS COMMUNICATION

APPROVED BY THE REGENTS
MAY 19, 2011

ACTION REQUEST

Subject: Research Agreement between the University of Michigan and the Arbor Research Collaborative for Health

Action Requested: Authorization to enter into the Agreement

Preamble:

A statutory conflict of interest situation was identified by the Division of Research Development and Administration while reviewing the research agreement 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 and approved by this Board and agreed to by the parties involved in this plan.

This proposed research Agreement ("Agreement") falls under the State of Michigan Conflict of Interest Statute because Dr. Robert Merion is both an employee of the University of Michigan ("University") and president and a member of the Board of Directors of Arbor Research Collaborative for Health ("ARBOR") and Dr. Robert Wolfe is both an employee of the University of Michigan and Vice President for Biostatistics at ARBOR. 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 Merion, Professor in the Department of Surgery, Division of Transplantation, is the president and a member of the Board of Director's of the ARBOR ("Company"). Dr. Robert Wolfe, Professor Emeritus of Biostatistics, is the Vice President of Biostatistics at ARBOR. Dr. Wolfe will oversee the financial and scientific involvement at ARBOR.

Nature of the Agreement:

The University has submitted a proposal to the National Institutes of Health (NIH) to develop and maintain a Data Coordinating Center (DCC) to support a consortium of investigators conducting epidemiological research on the medical and functional outcomes of individuals who have donated or received a living donor liver for transplantation. This DCC will address the current lack of comprehensive, systematic, national long-term study of live liver donor and recipient outcomes.

The University would like to subcontract a portion of the work under this contract to the Company, pursuant to University's Proposal No. 09-PAF01680 entitled "Adult-
to-Adult Living Donor Liver Transplantation Study Data Coordinating Center” and to University’s Proposal No. 10-PAF00306 entitled “Living Donor Liver Transplant Data Coordinating Center”.

As Principal investigator, Dr. Merion will have responsibility for the overall direction of the project, supervision of the effort and activities of all DCC faculty and staff personnel, maintenance of close collaborative relationships with the consortium’s clinical transplant centers and with the NIDDK Project Scientist, and ensure that the DCC provides robust and high quality support for the achievement of the research objectives of the project.

Agreement Terms:

The terms of the Agreement will conform to University policy. Under the project, a total subcontract of $220,344 is anticipated to cover a period of 5 years from September 2009 through August 2014. In the event of an amendment, University procedures for approval of these changes will be followed and additional conflict of interest review will be done as appropriate.

Impact of the Agreement:

The Agreement will enable the University to meet the Specific Aims originally submitted and approved by the National Institutes of Health.

Recommendation:

This matter has been reviewed and approved by the Medical School Conflict of Interest Board. In light of the disclosure made in this document and our finding that the Agreement was negotiated in conformance with University practices, I recommend that the Board of Regents approve the University entering into this Agreement with the ARBOR.

Respectfully submitted,

[Signature]

Stephen R. Forrest
Vice President for Research

May 2011