

THE UNIVERSITY OF MICHIGAN

REGENTS COMMUNICATION

Approved by the Regents

April 15, 2010

ACTION REQUEST

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

Action Requested: Authorization to enter into the Amendment to Agreement

Preamble:

A statutory conflict of interest situation was identified by the Division of Research Development and Administration while reviewing the proposed Amendment to Agreement. This then triggered a review by the Medical School Conflict of Interest Board. A plan for management of the possible risks associated with the conflicts of interest was then developed and approved by the Board and agreed to by the parties involved.

The proposed Amendment to Agreement ("Agreement") falls under the State of Michigan Conflict of Interest Statute because Drs. Robert Merion and Robert Wolfe are both employees of the University of Michigan ("University") and Arbor Research Collaborative for Health ("ARCH"). ARCH is an entity that conducts studies in epidemiology and public health. 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:

The University has an ongoing Agreement with ARCH for a research project entitled International Dialysis Outcomes and Practice Patterns (I-DOPPS). The current Principal Investigator for the project is Dr. Rajiv Saran, Associate Professor in the Department of Internal Medicine in the Medical School.

Nature of the Agreement:

The I-DOPPS project includes an Agreement, and prior amendments thereto, with ARCH. The Agreement is for participation in various aspects in support of the I-DOPPS project in the disciplines of medicine, nephrology, epidemiology, biostatistics and health economics. Scientific expertise has/will be provided in the areas of study design, instrument development, sampling methodology, study implementation and management, data management, statistical analysis, and publication.

Agreement Terms:

The Amendment adds \$149,740 of funding to the I-DOPPS project, bringing the total funding to \$2,675,316 and extends the period of performance to December 31, 2010. The University's standard contract provisions continue to apply. Since research agreements are often amended, the Agreement as amended continues to include provisions for changes in time, amount, and scope. University procedures for approval of these changes will be followed and additional conflict of interest reviews will be done as appropriate.

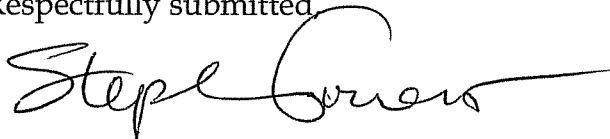
Impact of the Agreement:

The Agreement will permit the continued participation of the University in this important research into dialysis outcomes.

Recommendation:

This matter has been reviewed and approved by the Medical School Conflict of Interest Board. In light of the disclosure and our finding that the Agreement was negotiated in conformance with standard University practices, I recommend that the Board of Regents approve the Amendment to the Agreement between the University and Arbor Research Collaborative for Health.

Respectfully submitted,

A handwritten signature in cursive script that reads "Stephen R. Forrest". The signature is written in black ink and is positioned below the text "Respectfully submitted,".

Stephen R. Forrest  
Vice President for Research

April 2010