THE UNIVERSITY OF MICHIGAN

REGENTS COMMUNICATION

Approved by the Regents September 17, 2009

ACTION REQUEST

Subject:

Master Roundtable Research Agreement between the University of Michigan and the Center for Healthcare

Research and Transformation

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 proposed agreement. This then triggered a review by the OVPR Conflict of Interest Review Committee and/or the Medical School Conflict of Interest Board. A plan for management of the possible risks associated with the conflicts of interest will be developed by the Committee and/or Board and agreed to by the parties involved.

The proposed Master Roundtable Research Agreement ("Agreement") falls under the State of Michigan Conflict of Interest Statute because the Center for Healthcare Research and Transformation ("CHRT") is housed at University of Michigan ("University") and CHRT staff are University employees. 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:

CHRT is a 501(c)(3) organization, housed at the University, and is a joint venture between the University and Blue Cross Blue Shield, which was created when MCARE was sold last year ("Company"). The Company wishes to enter into a Master Research Agreement with the University.

Agreement Terms:

Dr. Gary Freed, Professor of Pediatrics, will be the Principal Investigator for the first project funded under the Master Agreement at the University. The Master Agreement is for various projects to be funded over a five-year period with the total authorization not to exceed \$5,000,000. The subcontract includes a provision for extensions of the time period and scope of work and is likely to be expanded to include additional projects. 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 OVPR Conflict of Interest Review Committee and/or Medical School Conflict of Interest Board will be done on a project-by-project basis.

Impact of the Agreement:

The Master Agreement will allow the University and the Company to specify projects that the University will conduct under the terms of the Master Agreement. The first agreement enables research to be performed regarding observation protocols to provide extended emergency department treatment and observation care to children within the existing structure of the pediatric emergency department. The key objectives are to describe clinical outcomes among patients who are treated according to an observation protocol, examine the impact of observation protocols on emergency department patient flow and inpatient capacity, evaluate emergency department inpatient length of stay and cost parameters concerning patients who are treated on an observation protocol versus those eligible for observation, and evaluate the acceptability of observation protocols and barriers to protocol utilization.

Recommendation:

These matters will be reviewed by the OVPR Conflict of Interest Review Committee and/or 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 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 Agreements will be negotiated in conformance with standard University practices, I recommend that the Board of Regents approve of the University's entering into this Master Roundtable Research Agreement with the Center for Healthcare Research and Transformation.

Respectfully submitted,

Stephen R. Forrest

Vice President for Research

September 2009