THE UNIVERSITY OF MICHIGAN

Approved by the Regents September 17, 2009

REGENTS COMMUNICATION

ACTION REQUEST

Subject:

Master Agreement between the University of Michigan and

Therapeutic Systems Research Laboratories, Inc.

Action Requested: Authorization to enter into Master Agreement

Preamble:

A statutory conflict of interest situation was identified by Division of Research Development and Administration while reviewing the proposed agreement. This then triggered a review by the OVPR Conflict of Interest Review Committee. A plan for management of the possible risks associated with the conflict of interest will be developed by the Committee and agreed to by the parties involved.

This proposed Master Agreement falls under the State of Michigan Conflict of Interest Statute because Dr. Gordon L. Amidon is both an employee of the University of Michigan ("University") and an owner of Therapeutic Systems Research Laboratories, Inc. ("TSRL"), and Dr. Phillip E. Kish is both an Adjunct Assistant Research Scientist at the University and an employee of TSRL. 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. Gordon L. Amidon, a Professor of Pharmacy and Professor of Pharmaceutical Sciences, College of Pharmacy, is an owner of TSRL. Dr. Phillip E. Kish is an Adjunct Assistant Research Scientist of Neurosurgery, Medical School and an employee of TSRL. TSRL wishes to have the University participate in various projects that TSRL will support independently or from grants from federal agencies, and which may be related to technology licensed or optioned to TSRL by the University. The role of any particular University investigator and/or Professor Amidon in each project will be described in a separate project statement and a conflict of interest management plan.

Agreement Terms:

The University will enter into a Master Agreement with the TSRL 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 \$1,000,000. The University will use standard sponsored 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. TSRL has supported eight projects at the University since 2004. The Master Agreement will allow the University and TSRL to specify projects that the University will conduct under the terms of 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 OVPR Conflict of Interest Review Committee 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 to explore and further develop the technology licensed to TSRL from the University. It also provides for ongoing support and collaboration between the University and a University start-up company.

Recommendation:

These matters will be reviewed by the OVPR Conflict of Interest Review Committee 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 is negotiated in conformance with standard University practices, I recommend that the Board of Regents approve of the University entering into this Master Agreement with Therapeutic Systems Research Laboratories, Inc.

Respectfully submitted,

Stephen R. Forrest

Vice President for Research

September 2009