Subject: Master Agreement between the University of Michigan and Tissue Regeneration Systems, Inc.

Action Requested: Authorization to enter into Master Agreement

Preamble:

A statutory conflict of interest situation was identified by the Division of Research Development and Administration while reviewing the current proposed project that 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 was then developed by this Committee and agreed to by the parties involved.

This proposed Master Agreement falls under the State of Michigan Conflict of Interest Statute because Drs. Scott Hollister, Frank LaMarca, Stephen Feinberg, Suman Das, and Chia-Ying Lin are all employees of the University of Michigan ("University") and partial owners of Tissue Regenerative Systems, Inc. ("TRS"). 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:

Drs. Scott Hollister, an Associate Professor in Biomedical Engineering, Frank LaMarca, a Clinical Assistant Professor in Neurosurgery, Stephen Feinberg, a Professor in Oral and Maxillofacial Surgery Department, Suman Das, an Assistant Professor in Mechanical Engineering, and Chia-Ying Lin, a Research Assistant Professor in the Department of Neurosurgery, are all partial owners of a for-profit company called TRS. TRS was formed to focus on developing integrated structural and surface modified materials that can serve as load bearing biologic delivery platforms for skeletal reconstruction, with applications in spine, craniofacial and orthopedic markets. TRS wishes to fund research projects at the University from time to time. The roles of Drs. Hollister, LaMarca, Feinberg, Das and Lin in each project will be described in a project statement and a conflict of interest management plan.
Agreement Terms:

The University will enter into a Master Agreement with TRS 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 $2,000,000. 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. The Master Agreement will allow the University and TRS to specify projects that the University will conduct under the terms of the master agreement. Since 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 conflict of interest review 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 structural and surface modified materials that can serve as load bearing biologic delivery platforms for skeletal reconstruction, with applications in spine, craniofacial and orthopedic markets.

Recommendation:

These matters will be reviewed and approved by the Office of the Vice President for Research 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's entering into this master agreement with TRS.

Respectfully submitted,

[Signature]

Stephen R. Forrest
Vice President for Research

May 2008