

ACTION REQUEST

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

Action Requested: Authorization to enter into Agreement

Preamble:

A statutory conflict of interest situation was identified by the Office of Research and Sponsored Projects while reviewing the Proposal Approval Form which then triggered a review by the Medical School Conflict of Interest Board and the UMOR Conflict of Interest Review Committee. A plan for management of the possible risks associated with the conflict of interest was then developed and approved by the Board and Committee and agreed to by the parties involved.

This proposed research agreement ("Agreement") falls under the State of Michigan Conflict of Interest Statute because Professors Frank La Marca, Steven Goldstein, and Stephen Feinberg are all employees of the University of Michigan ("University"), and partial owners of Tissue Regeneration Systems, Inc. ("TRS"). The law permits such an Agreement provided it is disclosed to the Board of Regents ("Regents") of the University of Michigan and approved in advance by a 2/3 vote.

Background:

Dr. Frank La Marca, an Associate Professor of Neurosurgery, Dr. Steven Goldstein, a Professor of Orthopaedic Surgery, and Dr. Stephen Feinberg, a Professor in Oral and Maxillofacial Surgery, are all partial owners of a for-profit company called TRS (the "Company"). The Company 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. The Company wishes to fund a project entitled "Early Bone Response to Implants" (ORSP# 16-PAF02250) in the Orthopaedic Surgery Department under the direction of Dr. Kenneth Kozloff. The purpose of this project is to explore and measure the response of bone to femoral implants.

Agreement Terms:

The terms of the Agreement conform to University policy. The period of performance for the project is approximately one (1) year. The amount of funding support will not exceed \$45,167. Since research projects are often amended, this agreement includes a provision for changes in time and scope. 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 support an effort by Dr. Kenneth Kozloff to use his expertise and University laboratory, as well as other University resources to explore and measure the response of bone to femoral implants. Specifically, he will monitor and measure the osteointegration of bone as a function of a variety of experimental conditions. Using biomechanical testing, advanced imaging and histologic analysis, the effect of implant surface, material properties, and initial interface conditions will be evaluated.

Recommendations:

This matter has been reviewed and approved by the Medical School Conflict of Interest Board and the UMOR Conflict of Interest Review Committee. In light of this disclosure and our finding that the Agreement was negotiated in conformance with standard University practices, I recommend that the Board of Regents approve the University's entering into this Agreement with Tissue Regeneration Systems, Inc.

Respectfully submitted,



S. Jack Hu
Interim Vice President for Research

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