

THE UNIVERSITY OF MICHIGAN
REGENTS COMMUNICATION

ACTION REQUEST

Subject: Subcontract Agreement between the University of Michigan and Innovative BioTherapies, 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. A plan for management of the possible risks associated with the conflict of interest was then developed and approved by the Board and agreed to by the parties involved.

This proposed agreement (“Agreement”) falls under the State of Michigan Conflict of Interest Statute because Professor H. David Humes is an employee of the University of Michigan (“University”), and a partial owner of Innovative BioTherapies, Inc. 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. H. David Humes, a Professor in the Department of Internal Medicine – Nephrology, is a partial owner of a for-profit company called Innovative BioTherapies, Inc. (the “Company”). The Company wishes to fund a National Institutes of Health (prime) SBIR Phase I project entitled “Use of a Biomimetic Membrane Device (BMD) to Decrease Delayed Graft Function in Renal Transplant” (ORSP #20-PAF06483) in the Department of Transplant Surgery under the direction of Dr. Alvaro Rojas-Pena. The purpose of this project is to perform testing of their novel Biomimetic Membrane Device (BMD) in renal transplant grafts from donors after circulatory death.

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 \$131,828. Since research projects are often amended, this agreement includes provisions 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. Rojas-Pena to use his expertise and University laboratory, as well as other University resources, to apply BMD therapy during and immediately after transplantation of kidneys from donors after circulatory death, perform data analysis, and publish results.

Recommendations:

This matter has been reviewed and approved by the Medical School Conflict of Interest Board. 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 Innovative BioTherapies, Inc.

Respectfully submitted,



Rebecca Cunningham
Vice President for Research

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