THE UNIVERSITY OF MICHIGAN

REGENTS COMMUNICATION

Approved by the Regents April 19, 2007

ACTION REQUEST

Subject:

Agreements between the University of Michigan and

Innovative Biotherapies, Inc.

Action Requested: Authorization to enter into Agreements

Preamble:

A statutory conflict of interest situation was identified by DRDA while reviewing the Proposal Approval Forms that 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 developed by the Board and agreed to by the parties involved in the projects.

This proposed agreements fall under the State of Michigan Conflict of Interest Statute because Dr. H. David Humes is both an employee of the University and a founder, owner director and officer of Innovative Biotherapies, Inc. (Company). 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. H. David Humes, Professor of Internal Medicine, Division of Nephrology is both an employee of the University and a founder, owner, director and officer of the Company. The Company wishes to have the University participate as a subcontractor under two grants that the Company will receive from federal agencies related to that technology such as the National Institutes of Health (NIH) and the Department of Defense. The role of Dr. Humes in each project is described in a project statement and a conflict of interest management plan.

Agreement Terms:

The terms of the proposed Agreements conform to University policies including those related to intellectual property, publication, and cost recovery. The first project is to be conducted over an initial twenty-four month period at an estimated total cost of \$110,007 including indirect cost at the University's negotiated federal indirect cost rate. The second project is to be conducted over an initial twelve-month period at an estimated total cost of \$206,828 including indirect cost at the University's negotiated federal indirect cost rate. Dr. Humes will serve as PI for both subcontracts. Since research agreements are often amended, the Agreements include provisions for changes in time, amount, and scope. University procedures for approval of these changes will be followed and additional review conflict of interest review will be done as appropriate.

Impact of the Agreement:

The agreements enable research to be performed in a timely manner to explore and further develop the technology licensed to the Company from the University to the engineering of therapy related to cytopheresis therapy and the development of a bioartificial wearable kidney. They provide for ongoing support and collaboration between the Medical School and a University start-up company.

Recommendation:

These matters have been reviewed and approved by the Medical School Conflict of Interest Board. In light of the disclosure made in this document and our finding that the agreements were negotiated in conformance with standard University practices, I <u>recommend</u> that the Board of Regents approve of the University entering into these agreements with Innovative Biotherapies, Inc.

Respectfully submitted,

Stephen R Forrest

Vice President for Research

April 2007