#### THE UNIVERSITY OF MICHIGAN

REGENTS COMMUNICATION

Approved by the Regents

September 20, 2007

## <u>ACTION REQUEST</u>

Subject:

Master 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 DRDA while reviewing the Proposal Approval Form 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 then developed by the Board and agreed to by the parties involved.

This proposed master agreement falls 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 M.D., 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 in various projects that the Company will support independently or from grants from federal agencies related to technology licensed or optioned to the Company by the University. The role of Dr. Humes 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 the Company 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 \$500,000. 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 Company has supported six projects at the University since its inception. The master agreement will allow the University and the Company 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 Medical School Conflict of Interest Board 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 the Company from the University to the engineering of therapy related to systemic inflammatory responses and other diseases and conditions. It also provides for ongoing support and collaboration between the Medical School and a University start-up company.

### Recommendation:

These matters will be reviewed by the Medical School Conflict of Interest Board, 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 Innovative Biotherapies, Inc.

Respectfully submitted,

Stephen R. Forrest

Vice President for Research

September 2007