

THE UNIVERSITY OF MICHIGAN
REGENTS COMMUNICATION

ACTION REQUEST

Subject: Extension of Master Agreement between the University of Michigan and Innovative Biotherapies, Inc.

Action Requested: Authorization to Extend the Master 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 extension to the master agreement (“Agreement”) falls under the State of Michigan Conflict of Interest Statute because Dr. H. David Humes is an employee of the University of Michigan (“University”), and a founder, partial owner, director, and officer of Innovative Biotherapies, Inc. (the “Company”). 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 founder, partial owner, director, and officer of a for-profit company called Innovative Biotherapies, Inc. (the “Company”). The Company was formed to commercialize technologies for therapy related to systemic inflammatory responses and other diseases and conditions from the University as disclosed in a previous Regental Action Request. The University entered into a Master Agreement with the Company after receiving Regental approval on September 20, 2007, for an initial five (5) year period with a total authorization not to exceed \$500,000. The University extended the Master Agreement with the Company until December 31, 2017, with a total amount not to exceed \$2,000,000, approved by the Regents on December 18, 2014. The University again extended the Master Agreement with the Company until December 31, 2022, with a total authorization not to exceed \$3,000,000, approved by the Regents on March 29, 2018. The Company wishes to continue to support research projects at the University related to research and development of technologies. The role of Dr. H. David Humes will be described in a project statement for each project and shall be subject to an approved conflict of interest management plan.

Agreement Terms:

The University will continue to use standard procedures for performance of projects as well as provisions implementing University and federal policies related to intellectual property and publications. The University will extend the Agreement with the Company until December 31, 2027, with a total authorization increased amount not to exceed \$4,000,000. The University will continue to use standard sponsored project accounting procedures to determine the cost of each project under this Agreement. Budgets will be reviewed and

approved by authorized representatives of the applicable department(s) and school(s)/college(s) where projects will be performed. The extended Agreement will allow the University and the Company to continue to specify projects that the University will conduct under the terms of the Agreement. Since sponsored projects are often amended, the Agreement will include provisions for changes in the time 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 extension will enable the continuation of research and testing that will assist the University in developing and commercializing technology licensed to the Company for therapy related to systemic inflammatory responses and other diseases and conditions. It also provides for ongoing support and collaboration between the University and a University of Michigan start-up company.

Recommendations:

These matters will continue to be reviewed and approved by the Medical School Conflict of Interest Board and a plan will be continued to manage the potential conflict of interest risks associated with each project that will be implemented under the terms of the Master Agreement extension prior to the University's approval of any individual project. In light of this disclosure and our finding that the Agreement extension will be negotiated in conformance with standard University practices, I recommend that the Board of Regents approve of the University extending this Agreement with Innovative Biotherapies, Inc.

Respectfully submitted,



Rebecca Cunningham
Vice President for Research

September 2022