

ACTION REQUEST

Subject: Master Agreement between the University of Michigan and JV Biolabs, LLC

Action Requested: Authorization to enter into Master Agreement

Preamble:

A statutory conflict of interest situation was identified by the Office of Research and Sponsored Projects, 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 will be 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 James Varani is an employee of the University of Michigan ("University"), and a partial owner of JV Biolabs, LLC ("JVB"). 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:

James Varani, Ph.D., a Professor in the Department of Pathology in the Medical School, is the partial owner and Chief Scientific Officer of a for-profit company called JVB (the "Company"). The Company was formed to commercialize the use of human cell, tissue and organ culture models, human-mouse xenograft models and animal models to provide efficacy and safety data on compounds in pre-clinical and early clinical stages of development technologies from the University as disclosed in a previous Regental Action Request. The Company wishes to support research projects at the University and desires to use facilities of the University for projects related to research and development of these technologies. The role of Dr. Varani 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 enter into an 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 Agreement will cover an initial five-year period, with a total authorization not to exceed \$2,000,000. The University will 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 Agreement will allow the University and the Company 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,

amount, 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 will facilitate research and testing that will assist the University in developing and commercializing technology that will provide safety and efficacy data for compounds in testing. It also provides for ongoing support and collaboration between the University and a University of Michigan start-up company.

Recommendations:

These matters will be reviewed and approved 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 approval of any individual project. In light of this disclosure and our finding that the Agreement will be negotiated in conformance with standard University practices, I recommend that the Board of Regents approve of the University entering into this Agreement with JV Biolabs, LLC.

Respectfully submitted,



S. Jack Hu
Interim Vice President for Research

February 2015