

THE UNIVERSITY OF MICHIGAN
REGENTS COMMUNICATION

ACTION REQUEST

Subject: Research Agreement between the University of Michigan and MeiraGTx Limited

Action Requested: Authorization to amend an Agreement

Preamble:

A statutory conflict of interest situation was identified by the Office of Research and Sponsored Projects 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 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 Robin Ali is an employee of the University of Michigan (“University”), and a partial owner of MeiraGTx Limited. 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:

Robin Ali, PhD, FmedScia, a Visiting Professor in the Department of Ophthalmology and Visual Science, is the Chief Scientific Officer and partial owner of a for-profit company called MeiraGTx Limited (the “Company”). The Company wishes to amend a research agreement previously approved by the Regents on March 29, 2018 to include the proposal entitled, “CTSU_ACD Gene Therapy for Achromatopsia (CNGB3)” (ORSP #19-PAF01699) in the Department of Ophthalmology and Visual Science under the direction of Dr. Cagri Besirli. The purpose of this amendment is for additional funding to support full field stimulus testing to assess the safety and efficacy of a recombinant adeno-associated virus vector (AAV2/8-hCARp.hCNGB3) for gene therapy of adults and children with achromatopsia owing to defects in CNGB3.

Agreement Terms:

The terms of the Amendment conform to University policy. The period of performance for the project is approximately two (2) years. The amount of funding support will be increased by \$10,913 and will not exceed \$563,161. Since research projects are often amended, this agreement includes a provision 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 amended Agreement will provide continued support of an effort by Dr. Besirli to use his expertise and University laboratory, as well as other University resources, to conduct this clinical trial.

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 amending this Agreement with MeiraGTX Limited.

Respectfully submitted,

A handwritten signature in blue ink, appearing to read 'S. Jack Hu', is positioned above the printed name.

S. Jack Hu
Vice President for Research

October 2018