

THE UNIVERSITY OF MICHIGAN
REGENTS COMMUNICATION

ACTION REQUEST

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

Action Requested: Authorization to enter into 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 research 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 Department of Ophthalmology and Visual Science, is the Chief Scientific Officer and partial owner of MeiraGTx Limited (the “Company”). The Company wishes to fund a project entitled “MGT008: Natural History Study for Achromatopsia Phenotyping and Genotyping Patients with Achromatopsia in Preparation for Gene Therapy Trials MGT010 Long term follow-up study of participants following an open label, multi-centre, Phase I/II dose escalation trial of a recombinant adeno-associated virus vector (AAV2/5-hRKp.RPGR) for gene therapy of adults and children with X-linked Retinitis Pigmentosa owing to defects in Retinitis Pigmentosa GTPase Regulator (RPGR)” (ORSP #20-PAF06592) in the Department of Ophthalmology and Visual Science under the direction of Dr. Cagri Besirli. The purpose of this project is to assess the longer-term safety of AAV2/5-hRKp.RPGR administered to participants in the RPGR trial.

Agreement Terms:

The terms of the Agreement conform to University policy. The period of performance for the project is approximately five (5) years. The amount of funding support will not exceed \$557,609. Since research projects are often amended, this agreement includes provisions 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 Agreement will support an effort by Dr. Besirli to use his expertise and University laboratory, as well as other University resources, to explore the longer-term efficacy of AAV2/5-hRKp.RPGR in improving visual and retinal function, quality of life, and protecting against sight impairment from retinal degeneration.

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 entering into this Agreement with MeiraGTx Limited.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Rebecca Cunningham', with a stylized, cursive script.

Rebecca Cunningham
Vice President for Research

May 2020