THE UNIVERSITY OF MICHIGAN REGENTS COMMUNICATION

ACTION REQUEST

Subject: Subcontract Agreement between the University of Michigan and

InheRET, Inc

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 agreement ("Agreement") falls under the State of Michigan Conflict of Interest Statute because Professors David F. Keren, Sofia Merajver, and Lee Schroeder, Ms. Lynn McCain, and Ms. Kara Milliron, are all employees of the University of Michigan ("University"), and partial owners of InheRET, Inc. 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:

David F. Keren, MD, a Clinical Professor in the Department of Pathology; Sofia Merajver, MD, PhD, a Professor in the Department of Internal Medicine – Hematology/Oncology; Lee Schroeder, MD, PhD, an Assistant Professor in the Department of Pathology; Lynn McCain, MHSA, PMP, a Senior Project Manager for the Genetic Testing Resource and Quality Consortium in the Department of Pathology; and Kara Milliron, MS, CGC, a Genetic Counselor in the Department of Pathology, are partial owners of a for-profit company called InheRET, Inc (the "Company"). The Company wishes to fund an NIH (prime) STTR Phase I project entitled "Inherited Risk Evaluation Tool - Clinical Neuroscience (InheRET - CNS)" (ORSP #20-PAF01064) in the Department of Psychiatry under the direction of Dr. Melvin McInnis. The purpose of this project is to expand the development of InheRET (Inherited Risk Evaluation Tool) to include the clinical neurosciences (InheRET-CNS).

Agreement Terms:

The terms of the Agreement conform to University policy. The period of performance for the project is approximately two (2) years. The amount of funding support will not exceed \$271,000. 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.

<u>Impact of the Agreement:</u>

The Agreement will support an effort by Dr. McInnis to use his expertise and University laboratory, as well as other University resources, for all matters related to the collection of clinical family history data, selection of probands and families able to participate in the family history data collection, organization of the databases, and evaluation of the data.

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 <u>recommend</u> that the Board of Regents approve the University's entering into this Agreement with InheRET, Inc.

Respectfully submitted,

Rebecca Cunningham

Interim Vice President for Research

September 2019

lulum