

THE UNIVERSITY OF MICHIGAN
REGENTS COMMUNICATION

ACTION REQUEST

Subject: Research Agreement between the University of Michigan and SeaStar Medical, 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 research agreement (“Agreement”) falls under the State of Michigan Conflict of Interest Statute because Professor H David Humes is an employee of the University of Michigan (“University”), and a partial owner of SeaStar Medical, 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:

Dr. H David Humes, a Professor in the Department of Internal Medicine – Nephrology, is a partial owner of a for-profit company called SeaStar Medical, Inc. (the “Company”). The Company wishes to fund a project entitled, “A Multi-Center Pilot Study to Assess the Safety and Efficacy of a Selective Cytopheretic Device (SCD) in Patients Developing Acute Kidney Injury (AKI) or Acute Respiratory Distress Syndrome (ARDS) Associated with COVID-19 Infection (SCD-005)” (ORSP #20-PAF08135) in the Department of Internal Medicine – Nephrology under the direction of Dr. Lenar Yessayan. The purpose of this project is to evaluate the safety and efficacy of SCD-2.5 treatment (up to 10 sequential 24-hour periods) on hospitalized patients with AKI or ARDS secondary to confirmed COVID-19, 60 days after treatment.

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 \$464,052. 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.

This agreement includes the provision that the University will be entitled to amend or terminate the agreement in the event that Regental approval is not obtained.

Impact of the Agreement:

The Agreement will support an effort by Dr. Yessayan to use his expertise and the Department of Internal Medicine – Nephrology, as well as other University resources, to evaluate the safety and efficacy of SCD-2.5 treatment (up to 10 sequential 24-hour periods) on hospitalized patients with AKI or ARDS secondary to confirmed COVID-19, 60 days after treatment.

Recommendations:

Due to the rapid spread of the novel coronavirus (COVID-19) and time sensitive nature of this agreement to assist in the treatment and mitigation of the spread, the Vice President for Research has reviewed this agreement and her signature on this action request signifies provisional approval for the University to enter into the agreement prior to Regental approval. 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 SeaStar Medical, Inc.

Respectfully submitted,



Rebecca Cunningham
Vice President for Research

September 2020