

THE UNIVERSITY OF MICHIGAN
REGENTS COMMUNICATION

ACTION REQUEST

Subject: Research Agreement between the University of Michigan and Sarcoma Alliance for Research through Collaboration

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.

This proposed research agreement ("Agreement") falls under the State of Michigan Conflict of Interest Statute because Denise Reinke is an employee of the University of Michigan ("University"), and the President and Chief Executive Officer of the Sarcoma Alliance for Research through Collaboration (SARC). 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:

Ms. Reinke, a Nurse Practitioner in the UMH Cancer Center, is the President and Chief Executive Officer of the non-profit company called SARC (the "Company"). The Company wishes to enter into a contract agreement entitled, "A Continuation Study of TH-CR-406/SARC021 for the Remaining Subjects Enrolled in TH-CR-406/SARC021 in the US" (ORSP #16-PAF06572) under the direction of Dr. Rashmi Chugh in the Department of Internal Medicine, Division of Hematology/Oncology, to provide continuation therapy with TH-302 for the single UM patient who obtained response or stabilization of disease with prior treatment during the randomized trial, TH-CR-406/SARC021 protocol. Ms. Reinke is not involved in any manner in this project and was not involved in any manner in the negotiation of the Agreement terms.

Agreement Terms:

The terms of the Agreement conform to University policy. The period of performance for the project is approximately one (1) year. The amount of funding support will not exceed \$2,550, unless the contract is amended to provide the patient with further treatment with TH-302. 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. Chugh to use her expertise and University facilities, as well as other University resources, to work collaboratively with the Company to provide continuation therapy to patients.

Recommendations:

The UMHS Compliance Office has put in place a management plan for this conflict which calls for Ms. Reinke to recuse herself from any University decisions involving a business relationship with the Company, and from participating in contract negotiations and approvals between the University and the Company. In light of this 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 Sarcoma Alliance for Research through Collaboration.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'S. Jack Hu', written in a cursive style.

S. Jack Hu
Vice President for Research

October 2016