

THE UNIVERSITY OF MICHIGAN
REGENTS COMMUNICATION

ACTION REQUEST

Subject: Subcontract 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 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 Ms. 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. Denise Reinke, a Nurse Practitioner in the UMH Cancer Center, is the President and Chief Executive Officer of a non-profit company called SARC (the “Company”). The Company wishes to fund a Janssen Scientific (prime) project entitled, “A Phase I Study to Evaluate the Safety of Trabectedin Administered as a 1- Hour Infusion in Ewing Sarcoma Patients in Combination with Low Dose Irinotecan and 3'-Deoxy-3'-18F Fluorothymidine (18F-FLT) Imaging” (ORSP #20-PAF04268) in the Department of Internal Medicine-Hematology/Oncology under the direction of Dr. Rashmi Chugh. The purpose of this project is to evaluate the safety of Trabectedin administered as a 1-hour infusion in Ewing sarcoma patients in combination with low dose Irinotecan and 3'-Deoxy-3'-18F Fluorothymidine (18F-FTL) imaging.

Agreement Terms:

The terms of the Agreement conform to University policy. The period of performance for the project is approximately nine (9) years. The amount of funding support will not exceed \$87,900. Since 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 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 therapy to patients.

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 Sarcoma Alliance for Research through Collaboration.

Respectfully submitted,



Rebecca Cunningham
Interim Vice President for Research

March 2020