

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 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 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 not-for-profit company called SARC (the “Company”). The Company wishes to enter into a contract agreement entitled, “A Phase II Randomized Controlled Trial of Neoadjuvant Pembrolizumab with Radiotherapy and Adjuvant Pembrolizumab in Patients with High-Risk, Localized Soft Tissue Sarcoma of the Extremity” (ORSP #17-PAF06615) under the direction of Dr. Scott Schuetze in the Department of Internal Medicine, Division of Hematology/Oncology, to provide therapy with pembrolizumab and radiotherapy to patients with soft tissue sarcomas. 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 (7) seven years. The amount of funding support will not exceed \$93,650. 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. Schuetze to use his 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,

A handwritten signature in blue ink, appearing to read 'S. Jack Hu', is positioned above the printed name.

S. Jack Hu  
Vice President for Research

June 2017