

THE UNIVERSITY OF MICHIGAN
REGENTS COMMUNICATION

ACTION REQUEST

Subject: Service 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. 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 enter into a service agreement entitled, “Comparative Effectiveness Study of Two Different Treatment Schedules of Denosumab as Long-term Maintenance Therapy in Patients with Giant Cell Tumor of Bone” (ORSP #18-PAF04760) in the Department of Internal Medicine – Hematology/Oncology under the direction of Dr. Scott Schuetze. The purpose of this project is to support Dr. Schuetze providing patient enrollment in a randomized trial to compare the effectiveness of two different schedules of denosumab treatment as prolonged maintenance therapy in patients with unresectable or recurrent giant cell tumor of bone, contribute to overall study conduct in collaboration with SARC, and provide expert consultation for orthopedic outcomes in patients participating in the clinical trial. 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 four (4) years. The amount of funding support will not exceed \$308,217. 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 compare the effectiveness of two different treatment schedules of denusumab as long-term maintenance therapy in patients with giant cell tumor of bone.

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

March 2018