THE UNIVERSITY OF MICHIGAN

Approved by the Regents June 19, 2008

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 DRDA while reviewing the Proposal Approval Form that then triggered a review by the Medical School Conflict of Interest Board. A plan for management of the possible risks associated with the conflicts of interest was then developed and approved by the Medical School Conflict of Interest Board.

This proposed subcontract agreement ("Agreement") falls under the State of Michigan Conflict of Interest Statute because Dr. Laurence Baker is both an employee of the University of Michigan ("University") and President of the Sarcoma Alliance for Research through Collaboration (SARC). The law permits such an Agreement provided it is disclosed to the executive officers and approved in advance by a 2/3 vote of the Regents.

Background:

Dr. Lawrence Baker, Professor of Internal Medicine, Division of Hematology/ Oncology and Director for Clinical Research, Comprehensive Cancer Center, is the Co-Founder, Executive Director, President and Director of SARC, a nonprofit research corporation located in Ann Arbor. SARC is funded primarily by contracts and gifts. Dr. Baker receives no compensation from SARC and has no financial interest in SARC.

Nature of the Agreement:

SARC has entered into agreements with Aventis and Eli Lilly, which includes financial support and a supply of the pharmaceutical drugs gemcitabine and docataxel (SARC Trial 006), which support clinical trials funded by SARC and conducted at major cancer centers including the University of Michigan. In addition to conducting this trial at the University of Michigan, SARC seeks database management services from the University, in the form of a Database Management Agreement, which will be under the direction of Daniel J. Clauw, Associate Dean, Clinical and Translational Research, who has no proprietary or other interest in SARC.

Agreement Terms:

The terms of the Agreement conform to University policy. Under the project, total funding of \$51,669 is anticipated to cover a period of five years. IRB approval will be obtained prior to the commencement of the work. Dr. Baker plays no role with regard to the University's performance of this Agreement and receives no remuneration from it.

Impact of the Agreement:

The Agreement will enable the University to participate in an important translational research effort to determine primarily whether the response rate among subjects with unresectable soft tissue sarcoma is superior with gemcitabine plus docataxel compared with gemcitabine alone, and secondarily, whether the percentage of subjects who are progression-free at 3 and 6 months is greater among subjects with unresectable soft tissue sarcoma treated with gemcitabine plus docataxel compared to those with gemcitabine alone.

Recommendation:

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 conforms to standard University practices, I <u>recommend</u> that the University of Michigan Regents approve of the University entering into this Agreement with the Sarcoma Alliance for Research through Collaboration.

Respectfully submitted,

Stephen R. Forrest

Vice President for Research

June 2008