Subject: Master Purchase Service Agreement between the University of Michigan and SWOG-Clinical Trials Initiative, LLC

Action Requested: Authorization to enter into Agreement

Preamble:

A statutory conflict of interest situation was identified by the Division of Research Development and Administration while reviewing the proposed agreement. This 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 will be developed by the Board and agreed to by the parties involved.

This proposed Master Purchase Service Agreement falls under the State of Michigan Conflict of Interest Statute because Dr. Laurence Baker is an employee of the University and SWOG-CTI (as sponsor); President of the Hope Foundation, which foundation, as the managing member of SWOG-CTI, exercises managerial control over it; and Chair of the Southwest Oncology Group, a cancer clinical trial research consortium hosted by the University. 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. Laurence Baker is Professor of Internal Medicine and a key person in the organizations that control SWOG-CTI ("Company"). The Company is a non-profit organization, formed as a Texas limited liability company for the purpose of accepting financial contributions from commercial donors to provide supplemental support to the Southwest Oncology Group's clinical research activities. Southwest Oncology Group's activities and trials are funded with U.S. government monies from the National Institute of Health/National Cancer Institute.

This proposed Master Purchase Service Agreement is the second instance of a master agreement between the Company and the University. The Company wishes to have the University participate in various projects that the Company will support independently or from grants from third parties. These projects will relate to government-funded clinical trials. Dr. Baker's role in each project will be described in a project statement and a conflict of interest management plan.
Agreement Terms:

The University will enter into a Master Purchase Service Agreement with the Company that will cover standard procedures for performance of projects as well as provisions implementing University and federal policies related to intellectual property and publication. The master agreement will cover an initial five-year period with a total authorization not to exceed $500,000. The University will use standard sponsored project accounting procedures to determine the cost of each project. Budgets will be reviewed and approved by authorized representatives of each department and school/college where projects are to be performed. The master agreement will allow the University and the Company to specify projects that the University will conduct under the terms of the master agreement. Because research projects are often amended, the master agreement includes provisions for changes in time, amount, and scope of each supported project. University procedures for approval of each project will be followed and additional review by the Medical School Conflict of Interest Board will be done on a project-by-project basis.

Impact of the Agreement:

The master agreement will enable research to be performed in a timely manner to explore and further advance clinical research in the prevention and treatment of cancer.

Recommendation:

These matters will be reviewed and approved by the Medical School Conflict of Interest Board and a plan will be developed prior to the University’s acceptance of any individual project. In light of the disclosure made in this document and our finding that the master agreement is negotiated in conformance with standard University practices, I recommend that the Board of Regents approve of the University entering into this master agreement with SWOG-Clinical Trials Consortium, LLC.

Respectfully submitted,

[Signature]

Stephen R. Forrest
Vice President for Research

September 2009