

THE UNIVERSITY OF MICHIGAN

REGENTS COMMUNICATION

Approved by the Regents

April 16, 2009

ACTION REQUEST

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

Action Requested: Authorization to enter into Master Agreement

Preamble:

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

This proposed Master Agreement falls under the State of Michigan Conflict of Interest Statute because Dr. Laurence Baker is an employee of the University of Michigan ("University") and the President of the Hope Foundation, which is the managing member of the SWOG-CTI, and the Chair of the Southwest Oncology Group, a cancer clinical trial research consortium hosted by the University of Michigan. 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. Baker is a Professor of Internal Medicine and a key person in the organizations that control SWOG-CTI ("Company"). The Company is a relatively new non-profit organization, formed in 2007, 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 cancer 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 Agreement is the first instance of an agreement between the Company and University. The Company wishes to have the University participate in various projects that the Company will support independently or from grants from third parties, related to studies ancillary 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 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 three and a half year period with a total authorization not to exceed \$5,000,000. 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.

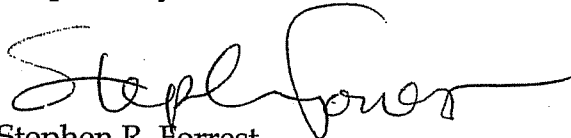
Impact of the Agreement:

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 by the Medical School Conflict of Interest Board and a plan will be developed to manage the potential conflict of interest risks associated with each project that will be implemented under the terms of the Master Agreement 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,



Stephen R. Forrest
Vice President for Research

April 2009