THE UNIVERSITY OF MICHIGAN REGENTS COMMUNICATION

ACTION REQUEST

Subject:

Sponsored Subaward Agreement between the University of Michigan and TSRL (Therapeutic Systems Research Labs),

Inc.

Action Requested: Authorization to enter into a Subaward Agreement

Preamble:

A statutory conflict of interest situation was identified by the Office of Contract Administration while reviewing the request to issue a sponsored subaward.

This proposed Research Subaward Agreement ("Agreement") falls under the State of Michigan Conflict of Interest Statute because:

- 1. Dr. Gregory Amidon is an employee of the University of Michigan ("University"), and a member of the Board of Directors at TSRL, Inc.
- 2. Dr. Gordon Amidon is an employee of the University, and has an equity interest in TSRL, Inc.

The law permits such an Agreement provided it is disclosed to the Board of Regents of the University and approved in advance by a 2/3 vote.

Background:

The University Of Michigan School of Medicine's Department of Internal Medicine, through its Division of Infectious Diseases, seeks approval to enter into an Agreement with TSRL, Inc. to collaborate in support of the Project entitled "A Molecularly Engineered Lectin for Use as a Treatment for Ebola and Marburg Viruses", as funded by Defense Threat Reduction Agency, Dept. of Defense (DoD), Prime Award No. HDTRA11510067. The overall purpose of the Project is to examine whether H84T BanLec can serve as a therapeutic/prophylactic agent for infection with filoviruses, and assess its molecular mechanism of action, using tissue culture models, wild-type viruses, and mouse and guinea pig experiments.

The proposed Agreement will fund TSRL, Inc. to collaborate with the University to develop the LC/MS/MS method for BanLec, execute pharmacokinetic studies, and provide data analysis and interpretation. Dr. Elke Lipka, a TSRL employee, is identified as a Senior/Key Person in the approved Prime Award, and will oversee all aspects of the pharmacokinetic studies, working with the staff at TSRL in designing experimental procedures, interpreting data and troubleshooting potential problems.

Agreement Terms:

The terms of the proposed Agreement will conform to University policy. The initial period of performance for the project is August 12, 2015 through August 12, 2016, with an expected total project period of August 12, 2015 through August 12, 2017.

The amount of initial funding shall not exceed \$49,443.00, and the expected total estimated amount shall not exceed \$99,609.00. Since research projects are often amended, this Agreement will include a provision for project related changes. 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 provide the scientific collaboration necessary for the University to carry out its obligations under its DoD Prime Award.

Recommendations:

UMOR's Conflict of Interest committee has reviewed this matter and determined that no formal management plan is required. In light of this determination and our finding that the Agreement is negotiated in conformance with standard University practices, I <u>recommend</u> that the Board of Regents approve the University's entering into this Agreement with TSRL, Inc.

Respectfull submitted,

Kevin P. Hegarty

Executive Vice President and Chief Financial Officer

April 2016