

SUBMITTED BY: STEPHEN M. LANIER, PH.D., VICE PRESIDENT FOR RESEARCH

**UNIVERSITY CONTRACT FOR LABORATORY SERVICES
FROM FUNCTIONAL FLUIDICS, LLC
A COMPANY OWNED BY A SCHOOL OF MEDICINE FACULTY**

RECOMMENDATION

The Administration recommends that the Board of Governors authorize the President or his designee to enter into a contract with Functional Fluidics, LLC, a Delaware limited liability company. The contract is for performing laboratory tests and to acquire blood samples acquired under the approval of the Wayne State University Institutional Review Board.

BACKGROUND

Patrick Hines, M.D., Ph.D., assistant professor, Department of Pediatrics, has developed novel processes and methods to measure whole blood adhesion and thrombus formation in a high throughput, in vitro diagnostic assay based on a microfluidics platform. The technology has been disclosed to the University and is described in a disclosure entitled "Process/Method for Risk Assessment, Diagnosis and Therapeutic Monitoring Conditions Predisposing Vascular Obstruction" (WSU 14-1203).

Functional Fluidics was founded by Dr. Hines and incorporated in Delaware in 2014. It is the intent of Functional Fluidics to further develop the assay technology and to become the leading contract research organization providing contract and direct service to academia, biotechnology and the pharmaceutical industry for measurement of adhesion and thrombosis. Wayne State University executed an exclusive license agreement with Functional Fluidics on November 4, 2014, the terms of which were presented and approved by the Board of Governors on June 27, 2014. Contracts for laboratory services was presented to and approved by the Board of Governors on October 10, 2014 and December 5, 2014.

The value of the assay technology has been quickly recognized by the pharmaceutical industry and Functional Fluidics has received a number of early contracts for the testing services. Functional Fluidics is still in the process of establishing the company laboratory. In order to satisfy the demand and to accelerate the commercialization of the technology, Functional Fluidics desires to contract with Wayne State University to have the university perform certain laboratory tests at the direction of Functional Fluidics.

Michigan Conflict of Interest law requires specific sunshine procedures in order for a University employee, or a company owned by a University employee, to contract directly or indirectly with the University:

- (A) The employee must disclose any pecuniary interest in the contract to the Board and the disclosure must be made a matter of record in the Board's proceedings.
- (B) The contract must be approved by a vote of not less than two-thirds of the full membership of the Board in open session.
- (C) The Board's minutes must report:
 - (i) The name of each party involved in the contract.
 - (ii) The terms of the contract, including duration, financial consideration between the parties, facilities or services of the public entity included in the contract, and the nature and degree of

- assignment of employees of the public entity for fulfillment of the contract.
- (iii) The nature of any pecuniary interest.

If the Board approves this Recommendation, the minutes will report as follows:

The Board of Governors authorized the President or his designee to enter into an agreement to provide up to \$126,000 in services with Functional Fluidics.

- (i) The parties involved in the contract are Wayne State University and Functional Fluidics, LLC.
- (ii) The contract will provide:
 - (a) Scope: Pending IRB approval, Wayne State University will acquire blood samples from patients with sickle cell disease for use by Functional Fluidics.
 - (b) Duration: The contract will be for one year.
 - (c) Financial Consideration: The amount of the contract will not exceed \$126,000, which includes indirect costs at a rate of 26%.
 - (d) University facilities to be utilized include Dr. Callahan's offices in the Department of Pediatrics at 3901 Beaubien, Detroit, 48201.
 - (e) Employees Assigned to the Services: Michael Callaghan, M.D., assistant professor of Pediatrics Hematology/Oncology Division for the School of Medicine who maintains a lab in the Elliman Building, will be the principal investigator for these services to prevent any conflicts of interest, real or perceived, that may arise in the conduct of the laboratory services.
- (iii) Dr. Hines' pecuniary interest consists of a current majority ownership of Functional Fluidics, LLC and he will therefore have the potential to financially benefit from the commercial success of the company.