

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

**UNIVERSITY CONTRACT WITH
AN OUTSIDE ORGANIZATION IN WHICH
A SCHOOL OF MEDICINE FACULTY MEMBER PARTICIPATES**

RECOMMENDATION

The Administration recommends that the Board of Governors authorize the President or his designee to enter into a purchase order agreement with Fraser Eye Center related to a master clinical study agreement from Pfizer. Inc.

BACKGROUND

Maysaa Basha, M.D., clinical associate professor of neurology in the School of Medicine, has a - contract from Pfizer, Inc. (Contract Number 421906, Protocol No. A0081096) that began on March 1, 2012 and will end November 30, 2017 with a total anticipated amount of \$70,967.

The study, “Prospective Randomized 12-Week Controlled Study of Visual Field Change in Subjects with Partial Seizures Receiving Pregabalin or Placebo” (hereinafter “Research Program”), will investigate changes in vision between subjects with epilepsy taking Pregabalin (Lyrica[®]) compared to subjects taking only a placebo. This study is not being done to see if Pregabalin improves seizures, but rather to see the effect Pregabalin may have on the patient’s vision. Research is needed to determine if there is a correlation between the use of this medication and any disruption in the peripheral vision exists.

Clinical studies under the agreement will be supported by a prime contract from Wayne State University to Fraser Eye Center. Mahdi Basha, D.O., ophthalmologist, owner of Fraser Eye Center and spouse of Maysaa Basha, M.D., will lead the clinical work at Fraser Eye Center.

By entering into an agreement, Fraser Eye Center will receive up to \$3500 through November 20, 2017 in support of clinical work to be performed by personnel at Fraser Eye Center.

The Financial Conflict of Interest Committee at Wayne State has met and reviewed the relationship and financial status of Mahdi Basha, D.O. with Fraser Eye Center and Maysaa Basha, M.D., and presented Dr. Mahdi Basha with a contract to sign to disclose this relationship and ownership. He has agreed to the conditions and signed this contract.

Wayne State University does not have any ownership interest in Fraser Eye Center.

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 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 authorizes the President or his designee to contract with Madhi Basha, D.O., owner of Fraser Eye Center, an organization that Maysaa Basha, M.D.'s, clinical associate professor of neurology in the School of Medicine, spouse owns, to perform work needed for a Pfizer, Inc. clinical study awarded to Wayne State University through a purchase order agreement with standard terms regarding the ownership of inventions developed during the Research Program.

- i. The parties involved in the contract are Wayne State University and Fraser Eye Center.
- ii. The contract will provide that:
 - a. Fraser Eye Center shall perform a service a purchase order agreement in an amount up to \$3500 (inclusive of standard overhead costs). The University will retain ownership of its discoveries relating to the technology resulting from the Research Program. Any unused funds will remain with the prime contract at the University;
 - b. The term of a purchase order agreement will extend through November 30, 2017 unless extended by the parties. The agreement may be terminated by the University in the event of an uncured breach of the agreement by Fraser Eye Center;
 - c. An employee of WSU, Prof Maysaa Basha, M.D., from the Department of Neurology, will function as the principal investigator.
- iii. Fraser Eye Center is a small, for-profit entity owned solely by Dr. Mahdi Bashi, spouse of Dr. Maysaa Basha. Because of this relationship, Dr. Maysaa Basha has the potential to financially benefit from the commercial success of the company.