

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

**UNIVERSITY SUBCONTRACT FOR LABORATORY SERVICES
FROM NEULINK, INC.
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 contract with NeuLink, Inc., a Michigan C-Corporation company. The contract will be to perform research and laboratory services related to preclinical studies of Fc-folate conjugates as a breast cancer therapeutic.

BACKGROUND:

Cecilia Speyer, Ph.D., assistant professor of surgery in the School of Medicine, has developed IgA-Fc-folate conjugates for targeting and destroying triple negative breast cancer (TNBC) cells. The technology has been disclosed to the University and is described in a disclosure entitled "IgA Fc-Folate Conjugates, Pharmaceutical Compositions and Methods to Treat Cancer," (Wayne State File #14-1221) and for which a patent application (US Ser. No. 15/227,747) has been filed by Wayne State University.

NeuLink, Inc., incorporated in Michigan in 2013, was founded to develop and commercialize Fc-folate conjugates for the treatment of cancer and autoimmune disorders. Dr. Cecilia Speyer is the cofounder and majority owner of the company located at 2727 Second Ave, Suite 4105, Detroit, Michigan.

NeuLink, Inc. is the recent recipient of a Phase I Small Business Innovative Research (SBIR) grant from the National Institute of Child Health and Human Development of the National Institutes of Health, award number R43HD092295, entitled "A Platform for Safe, Noninvasive Prenatal Genetic Testing at Five Weeks of Pregnancy," which includes a subcontract for services to Wayne State University.

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 a contract with NeuLink, Inc.

- (i) The parties involved in the contract are Wayne State University and NeuLink, Inc.

- (ii) The contract will provide that:

- (a) Scope: Wayne State University will be responsible for the procurement of specific (Prkdc-scid) mice and testing the efficacy of the Fc-folate conjugates on tumor cell killing in these mice in accordance with Wayne State University IACUC protocol entitled "Fc-Folate Conjugates for the Treatment of Triple Negative Breast Cancer" (Protocol 17-07-298, approved September 1, 2017). Pending approval of an amendment for IRB Protocol # 123016MP4E, Wayne State University will acquire the breast tissue from TNBC patients for isolating cancer cells to test in the mouse tumor models described in (a).

- (b) Duration: The contract will be for twelve months with an effective start date of December 1, 2017.

- (c) Financial Consideration: The amount of the contract is for \$124,736.88 which includes indirect costs at a rate of 54%.

- (d) University Facilities to be Utilized: University facilities to be utilized for the laboratory research include Dr. Cecelia Speyer's lab in the Department of Surgery, School of Medicine located at 832 HWCRC and 427 Lande.

- (e) Employees Assigned to the Services: Dr. Cecelia Speyer, assistant professor of surgery, will be the principal investigator on the project and will oversee a lab technician at the university. Dr. Mary Kosir, professor of surgery and oncology at Wayne State University, is the breast cancer surgeon in charge of patient recruitment. Dr. Sudeshna Bandyopadhyay, associate professor of pathology at Wayne State University will be the pathologist responsible for procuring the patient tissue. Dr. Lance Heilbrun, professor in the Biostatistics Core at Karmanos Cancer Institute, will be responsible for the statistical component of this project.

- (iii) Dr. Speyer's pecuniary interest consists of a current majority (51%) ownership of NeuLink, Inc., with family members holding the remaining 49% equity. Dr. Speyer will therefore have the potential to financially benefit from the commercial success of the company. Dr. Speyer has filed a Financial Conflict of Interest with the Office of Research Integrity.