

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

**UNIVERSITY SUBCONTRACT ON NATIONAL INSTITUTES OF HEALTH GRANT
WITH A COMPANY PARTIALLY OWNED BY
COLLEGE OF ENGINEERING FACULTY MEMBER AND EMPLOYEE**

RECOMMENDATION

The Office of the Vice President for Research recommends that the Board of Governors authorize the President or his designee to enter into a sponsored research agreement with Cell and Molecular Tissue Engineering, LLC (CMTE), a company located in Avon, CT, a company partially owned by Ulrike Klueh, Ph.D., associate professor of Biomedical Engineering in the College of Engineering. The subcontract will be used to perform research as part of a National Institute of Diabetes and Digestive and Kidney Disease (NIH/NIDDK) grant awarded to Wayne State University, *Infusion device optimization by addressing root causes of the inflammatory response (project number 1R01DK129681)*.

BACKGROUND

Ulrike Klueh, Ph.D., associate professor of Biomedical Engineering in the College of Engineering, is the co-founder of Cell and Molecular Tissue Engineering, LLC (CMTE) together with Dr. Donald L. Kreutzer, CEO.

The National Institute of Diabetes and Digestive and Kidney Disease awarded Dr. Klueh a \$2.66 million award, *Infusion device optimization by addressing root causes of the inflammatory response*, that aims to address challenges in extending the life space of diabetes infusion pumps and to reduce inflammation and secondary fibrosis caused by current diabetes device technology. The research could result in transforming current diabetes management practices that would achieve the goals of increasing the lifespan of insulin infusion devices and sustaining a tissue site available for future recurrent insulin administrations.

Dr. Klueh and the Department of Biomedical Engineering wish to enter into a subcontract agreement on this NIH award with CMTE to allow Dr. Kreutzer to provide both technical support for the studies as outlined in the proposal, as well as provide quantitative histopathology and immunohistochemistry evaluation input of the mouse and porcine tissue samples. Dr. Kreutzer is a leader in immunopathology and co-inventor of related innovations and patents as outlined in the research proposal. Dr. Kreutzer is a research scientist with nearly 240 peer reviewed publications in the area of inflammation and wound healing, the topic of the grant proposal.

CMTE was founded in 2010 as a joint venture by Drs. Klueh and Kreutzer. The goal of CMTE is to develop novel implantable devices and materials that can be used for the diagnosis and treatment of human and animal diseases. CMTE also focuses on the design and development of

coating technologies that enhance biocompatibility of implanted devices, i.e. enhance and extend the function and lifespan of implantable devices and materials that are used in vivo. This also includes the development of new implantable devices that would benefit from these technologies. The current focus of CMTE is to develop technologies that will enhance and extend the lifespan of implantable biosensors, insulin pumps, drug delivery systems and surgical meshes used in reconstructive surgery, such as hernia operations.

WSU's College of Engineering plans to enter into a subcontract agreement with CMTE for a research project totaling approximately \$84,920.

The purpose of the research subcontract is for CMTE to provide digital imaging of all histopathology and immunohistochemistry related to the mice and porcine studies, both qualitatively and quantitatively. Based on this analysis CMTE will provide guidance and advise the WSU team on inflammation studies.

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:

1. The employee must disclose any pecuniary interest in the contract to the Board of Governors and the disclosure must be made a matter of record in the Board's proceedings.
2. The contract must be approved by a vote of not less than two-thirds of the full members of the Board in open session.
3. The Board's minutes must report:
 - i. The name of each party 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 authorized the President, or his designee, to contract with Cell and Molecular Tissue Engineering, LLC (CMTE) of which Ulrike Klueh, Ph.D., associate professor of Biomedical Engineering in the College of Engineering at Wayne State University, is a co-founder.

- i. The parties involved in the contract are Wayne State University and CMTE.
- ii. The contract will provide:
 - a. Scope: Wayne State will subcontract to CMTE for the performance of a research program for Dr. Donald Kreutzer, CEO of CMTE, to assist in the leukocyte analysis

including all histopathology and immunohistochemistry related to the mouse and porcine studies, both qualitatively and quantitatively. The contract will be a standard research agreement and any inventions developed under this subcontract, whether created by WSU employees working at CMTE or at the university, will be owned by WSU, and CMTE will have an option to acquire a license to them. Additional information is still needed from CMTE and potential issues need to be resolved prior to signing the agreement. The University will reserve the right to not enter into the subcontract if the information is not provided and the issues are not resolved. The subcontract will also be subject to any required conflict of interest management plans developed by the Conflict of Interest committee.

- b. Term: The contract will have a term of approximately 5 years, with an estimated start date in June or July of 2022.
 - c. Financial Consideration: The subcontract to CMTE will be \$84,920. CMTE's services will not utilize Wayne State University facilities and personnel.
- iii. Dr. Kleuh's pecuniary interest consists of an ownership interest in CMTE. She currently holds 50% of CMTE's equity interest and will therefore have the potential to financially benefit from the commercial success of the company. She will not receive compensation from CMTE for services on this project.