October 13, 2023

TO: President Michael Drake
The Regents of the University of California

RE: Chancellor’s Determination and Rationale for Approval of Research Funded by Philip Morris Products S.A.

I write to advise you in accordance with Regent Policy 2309, that I have approved two research projects on the Berkeley campus to receive funding from Philip Morris Products S.A., as part of the Berkeley Sensor and Actuator Center (BSAC) Industry Affiliates Program. The projects will be led by UC Berkeley faculty, Professor Liwei Lin and Professor Ali Javey.

Regent Policy 2309: Policy Requiring Special Review/Approval Procedures Prior to University Submission of Research Proposals to Tobacco Industry Funders, requires that each UC campus establish a process for ensuring that any proposal submitted to a company whose primary business is the manufacture and sale of tobacco products, or any agency that is substantially controlled or acting on behalf of a tobacco company, must first undergo scientific peer review.

Funding for Professors Lin and Javey’s projects do not follow a typical sponsored research funding model. In this instance, Philip Morris provides block funding to BSAC through the Center’s Industry Affiliates Program. Funding decisions are made by BSAC’s (faculty) governing board based on brief proposals submitted by interested BSAC-affiliated faculty.

While Philip Morris does not have the authority to approve or deny research proposals under this arrangement, the Berkeley campus nevertheless decided to follow its normal protocol with respect to receipt of tobacco industry funding. Our Vice Chancellor for Research Office appointed two committees of distinguished UC Berkeley faculty members with subject matter expertise relevant to each of the proposals and briefed the committees on the requirements of the Regents Policy.

The review committees advised that both proposals exhibit the requisite scientific merit and scholarly independence, and recommended that both be allowed to proceed. These recommendations were reviewed and endorsed by Vice Chancellor for Research, Kathy Yelick. I have reviewed and concur with VCR Yelick’s recommendation.

This letter confirms my approval of BSAC’s request on behalf of Principal Investigators Lin and Javey and satisfies the Regent Policy 2309 requirement for a written determination.

Sincerely,

Carol T. Christ
Chancellor
Attachments:
   Review Committee Reports

CC: Theresa Maldonado, Vice President for Research & Innovation
    Deborah Motton, Executive Director, Research Policy Analysis & Coordination
    Tricia Lyall, Secretary and Chief of Staff to the Regents
UC Berkeley Evaluation of Proposed Tobacco-Related Research Funding, Pursuant to Regent Policy 2309

Funder: Philip Morris Products S.A.
Mechanism: Berkeley Sensor and Actuator Center (BSAC) Industry Affiliate Program

Project:
Pl: Dr. Ali Javey
Project Title: Fingertip Sweat Analyzers with Disposable Electrochemical Transducers

Review Committee:
Dr. Daniel Fletcher, Professor, Department of Bioengineering
Dr. Seung-Wuk Lee, Professor, Department of Bioengineering

Review Committee Findings:
Dr. Ali Javey's proposal, titled "Fingertip Sweat Analyzers with Disposable Electrochemical Transducers," aims to develop a practical and convenient fingertip-based biosensor for continuous monitoring of clinically relevant biomarkers. By integrating reusable electronic modules with disposable transducers, this approach addresses real-world health challenges in a novel way. Despite the availability of various types of wearable sensors for heart rate, blood oxygenation and other measures, the lack of noninvasive chemical sensors has hindered a broad set of healthcare applications that rely on molecular measurements. Previously, Dr. Javey has demonstrated wearable electrochemical sensors for sweat analysis, offering stability and reliability through diverse form factors. His collaborations with VTT (in Finland) also facilitated cost-effective mass production. Sensors for ions, metabolites, heavy metals, vitamins, and drugs show promising correlations through off-body measurements, including detecting cystic fibrosis and dehydration-related ion shifts. Innovative microfluidic patches enable continuous, at-rest sweat monitoring, enhancing physiological insight.

The proposal briefly outlines Dr. Javey's plan to advance his successful work by integrating fingertip-based sweat sensors for touch-based single-point measurements. The proposal envisions a versatile analyzer with interchangeable stick-on transducers for user-friendly disposability and reusability. He plans to develop robust electrical sensor components, test them for sodium ion sensing, and expand to other chemicals such as nicotine. Off-body tests with known concentrations will be used to calibrate sensors and assess variability, signal drift, and interfacing over attaching/detaching cycles. Reviewers conclude that this proposed work does not have any conflict of interest issue with the tobacco industry. The successful outcome of the proposed work will offer practical, cost-effective health monitoring through user-friendly components and reusable analyzers.

Date received: 8/29/2023
UC Berkeley Evaluation of Proposed Tobacco-Related Research Funding, Pursuant to Regent Policy 2309

Funder: Philip Morris Products S.A.
Mechanism: Berkeley Sensor and Actuator Center (BSAC) Industry Affiliate Program

Project:
PI: Dr. Liwei Lin
Project Title: A Miniaturized Ultrasound Bone Age Assessment Device

Review Committee:
Dr. Tony Keaveny, Professor, Department of Mechanical Engineering and Bioengineering
Dr. Mary Cooper Scott, Assistant Professor, Department of Materials Science and Engineering
& Faculty scientist at Molecular Foundry, LBNL
Dr. Shaofan Li, Professor, Department of Civil and Environmental Engineering

Review Committee Findings:
The objective of this work is to perform initial work on developing a miniaturized and low-cost ultrasonic device using microelectromechanical systems that can be further refined for eventual clinical use in assessment of bone age in children. The research team has used piezoelectric micromachined ultrasound transducers (PMUTs) for many years and will apply this technology to this new application.

Most of the project effort will be on the design, simulation, fabrication, characterization, and testing of the PMUTs. They plan to use 3D printing to make a simple solid phantom with slots of different widths as the mold insert, all to simulate bone at different ages. By adding PDMS solutions onto the mold insert and detaching the PDMS structure after the curing process, the researchers can construct simple phantoms to emulate tissues and bones with different tissue thicknesses to characterize the different PMUT devices. This team is well experienced in constructing such phantoms. More complex geometries will be followed to emulate human bones for bone age assessments. Tests will be repeated on the same phantom 10 times to statistically characterize the mean and standard deviations of the gap widths (and other parameters) by using the prototype PMUTs device. The imaging-based measurements from the prototype PMUTs device will be compared with the direct measurements in the phantoms. PMUT parameters will be varied as needed in order to provide accurate measurements. The metric of success is to demonstrate no significant difference.

Altogether, this committee found that the proposed work uses sound methodology and has been designed appropriately to enable the researchers to reach their proposed objectives and scientifically valid conclusions. Therefore, we recommend approval of this project for submission.

Date received—9/18/2023