

THE UNIVERSITY OF MICHIGAN
REGENTS COMMUNICATION

ACTION REQUEST

Subject: Project Agreements with the University of Michigan

Action Requested: Authorization to enter into or amend Agreements

Preamble:

Statutory conflicts of interest situations were identified by the Office of Research and Sponsored Projects while reviewing Proposal Approval Forms that then triggered a review by the Medical School Conflict of Interest Board and/or the UMOR Conflict of Interest Review Committee. Plans for management of the possible risks associated with the conflicts of interest will be developed and approved by the Board and/or Committee and may require agreement by the parties involved at time of award.

These proposed project (e.g., research, sponsored activity, and/or subcontract) agreements (“Agreement”) and/or amendments to Agreements (“Amendments”) fall under the State of Michigan Conflict of Interest Statute because University of Michigan (“University”) employees have activities, relationships, or interests in the companies as described in Attachment A. The law permits such Agreements provided they are disclosed to the Board of Regents (“Regents”) of the University and approved in advance by a 2/3 vote.

Agreement Terms:

The terms of the Agreements and/or Amendments conform to University policy. The funding support will not exceed the amount reported in Attachment A for each Agreement and/or Amendment. Since projects are often amended, these Agreements and/or Amendments include provisions for changes in time and scope. University procedures for approval of these changes will be followed and additional conflict of interest review will be done as appropriate.

Impact of the Agreement:

The Agreements and/or Amendments will provide support of investigator’s effort to use their expertise and University laboratories, as well as other University resources, to execute the projects as reported in Attachment A.

Recommendations:

These matters have been reviewed and approved by the Medical School Conflict of Interest Board and/or the UMOR Conflict of Interest Review Committee. In light of this disclosure and our finding that the Agreements and Amendments were negotiated in conformance with standard University practices, I recommend that the Board of Regents approve the University’s entering into or amending the Agreements referenced in Attachment A.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Rebecca Cunningham', written in a cursive style.

Rebecca Cunningham
Vice President for Research

February 2021

Project #1

SBIR Phase I Subcontract Agreement between the University and Amphionic, LLC Reviewed by the UMOR Conflict of Interest Committee	
<u>Project Information</u>	
Title: Radiation dosimeter Utilizing an Ultrathin Amorphous-Silicon Layer	U-M Project ID: 21-PAF02378
Direct Sponsor: Amphionic LLC	Prime Sponsor: U.S. Department of Defense
Principal Investigator/Department: Mark Hammig, Nuclear Engineering and Radiological Sciences	
Project Duration: Ten (10) Months	Funding Support: \$27,118
Purpose: The purpose of this project is to demonstrate that it is feasible to utilize an a-Si cavity sensor as a dosimeter across the range of absorbed dose targeted.	
<p align="center"><u>University Employee; University Title; Relationship with Amphionic LLC</u></p> <ul style="list-style-type: none"> • Mark Hammig; Associate Research Scientist, Nuclear Engineering and Radiological Sciences; Partial Owner • Suneel Joglekar; Research Fellow, Nuclear Engineering and Radiological Sciences; CEO 	

Project #2

Amendment to Research Agreement between the University and Applied Materials, Inc. Reviewed by the UMOR Conflict of Interest Committee	
<u>Project Information</u>	
Title: Supplement: Neuromorphic Test Chip Collaboration	U-M Project ID: 21-PAF04783
Direct Sponsor: Applied Materials, Inc.	
Principal Investigator/Department: Wei Lu, Electrical Engineering and Computer Science – Electrical and Computer Engineering (EECS-ECE) Division	
Agreement Originally Approved by the Regents: March 28, 2019	
Current Project Duration: Eighteen (18) Months Additional Time: Thirteen (13) Months	Current Funding Support: \$789,909 Additional Funding: \$389,020
Purpose: The purpose of this amendment to add additional funds and time so that Dr. Wu may complete Cerebro2 chip testing and in-memory computing algorithm an architecture exploration.	
<p align="center"><u>University Employee; University Title; Relationship with Applied Materials, Inc.</u></p> <ul style="list-style-type: none"> • Stephen Forrest; Professor, EECS-ECE Division; Board of Directors Member 	

Project #3

**SBIR Phase I Subcontract Agreement between the University and Arcascope Inc.
Reviewed by the UMOR Conflict of Interest Committee**

Project Information

Title: Validation of a mobile application for sleep and circadian wellness in pregnant women

U-M Project ID: 21-PAF03953

Direct Sponsor: Arcascope Inc.

Prime Sponsor: National Institutes of Health

Principal Investigator/Department: Louise O'Brien, Neurology

Project Duration: One (1) Year

Funding Support: \$128,290

Purpose: The purpose of this project is to develop open-source sleep estimation models that are trained and tested on data collected from pregnant women.

University Employee; University Title; Relationship with Arcascope Inc.

- Daniel Forger; Professor, Mathematics; Partial Owner
- Kevin Hannay; Assistant Professor, Mathematics; Partial Owner

Project #4

**STTR Phase I Subcontract Agreement between the University and Courage Therapeutics, Inc.
Reviewed by the UMOR Conflict of Interest Review Committee**

Project Information

Title: Development of Therapeutic MC3R Agonist Peptides for the Treatment of Anorexia Nervosa

U-M Project ID: 21-PAF01289

Direct Sponsor: Courage Therapeutics, Inc.

Prime Sponsor: National Institutes of Health

Principal Investigator/Department: Roger Cone, Life Sciences Institute

Project Duration: One (1) year

Funding Support: \$175,034

Purpose: The purpose of this project is to characterize MC3R peptide agonists and determine their activity on food intake and weight gain.

University Employee; University Title; Relationship with Courage Therapeutics, Inc.

- Roger Cone; Vice Provost and Director of the Biosciences Initiative, Life Sciences Institute; Partial Owner

Project #5

Research Agreement between the University and Eli Lilly and Company Reviewed by the Medical School Conflict of Interest Board	
<u>Project Information</u>	
Title: CTSU_ACD: J2W-MC-PYAB (BLAZE-1) (3239-Albin)	U-M Project ID: 21-PAF03792
Direct Sponsor: Eli Lilly and Company	
Principal Investigator/Department: Owen Albin, Internal Medicine-Infectious Diseases	
Project Duration: One (1) Year	Funding Support: \$294,305
Purpose: The purpose of this project is to evaluate the impact of LY3819253 and LY3832479 on viral clearance and clinical outcomes in participants with COVID-19 illness. The data from this study will inform decisions for the clinical development of LY3819253 and LY3832479.	
<u>University Employee; University Title; Relationship with Eli Lilly and Company</u>	
<ul style="list-style-type: none">• Marschall Runge; Executive Vice President for Medical Affairs, Dean of the Medical School; Board of Directors Member	
COVID-19 Related Special Circumstances: Due to the rapid spread of the novel coronavirus (COVID-19) and time sensitive nature of this agreement to assist in the treatment and mitigation of the spread, the Vice President for Research reviewed this agreement and signified provisional approval on December 21, 2020 for the University to enter into the agreement prior to Regental approval. This agreement includes the provision that the University will be entitled to amend or terminate the agreement in the event that Regental approval is not obtained.	

Project #6

Research Agreement between the University and Eli Lilly and Company Reviewed by the Medical School Conflict of Interest Board	
<u>Project Information</u>	
Title: A-29228 – 2020 ACC Lilly Grantee Award	U-M Project ID: 21-PAF03961
Direct Sponsor: Eli Lilly and Company	
Principal Investigator/Department: Alison Narayan, Life Sciences Institute	
Project Duration: Two (2) Years	Funding Support: \$100,000
Purpose: The purpose of this project is to develop biocatalysts and their application in organic synthesis.	
<u>University Employee; University Title; Relationship with Eli Lilly and Company</u>	
<ul style="list-style-type: none">• Marschall Runge; Executive Vice President for Medical Affairs, Dean of the Medical School; Board of Directors Member	

Project #7

Second Amendment to Research Agreement between the University and Eli Lilly and Company Reviewed by the Medical School Conflict of Interest Board

Project Information

Title: CTSU_2019.122_Worden_JZJB_Lilly_Amendment 2

U-M Project ID: 21-PAF04290

Direct Sponsor: Eli Lilly and Company

Principal Investigator/Department: Francis Worden, Internal Medicine-Hematology/Oncology

Agreement Originally Approved by the Regents: December 5, 2019

First Amendment Approved by the Regents: May 21, 2020

Current Project Duration: Seven (7) Years

Additional Time: N/A

Current Funding Support: \$1,553,150

Additional Funding Support: \$10,460

Purpose: The purpose of this amendment to add additional funds so that Dr. Worden may continue to focus on comparing LOXO-292 to Cabozantinib or Vandetanib in Patients with RET-Mutant Medullary Thyroid Cancer.

University Employee; University Title; Relationship with Eli Lilly and Company

- Marschall Runge; Executive Vice President for Medical Affairs, Dean of the Medical School; Board of Directors Member

Project #8

Other Sponsored Activity between the University and Kinetica Labs, Inc. Reviewed by the UMOR Conflict of Interest Review Committee

Project Information

Title: Force Data Collection

U-M Project ID: 21-PAF04729

Direct Sponsor: Kinetica Labs, Inc.

Principal Investigator/Department: SangHyun Lee, Civil and Environmental Engineering

Project Duration: One (1) Year

Funding Support: \$68,219

Purpose: The purpose of this project is to collect a large force dataset from manual work simulated in the lab environment.

University Employee; University Title; Relationship with Kinetica Labs, Inc.

- SangHyun Lee; Professor, Department of Civil and Environmental Engineering; Partial Owner
- Dave Gregorka; Mentor-in-Residence, Office of Technology Transfer; Board of Directors Member

Project #9

**Research Agreement between the University and Labyrinth Biotech Inc.
Reviewed by the UMOR Conflict of Interest Review Committee**

Project Information

Title: Testing of inertial microfluidic device for cancer cell isolation

U-M Project ID: 20-PAF03859

Direct Sponsor: Labyrinth Biotech Inc.

Principal Investigator/Department: Sunitha Nagrath, Chemical Engineering

Project Duration: Two (2) Years

Funding Support: \$133,922

Purpose: The purpose of this project is to perform experiments to verify the recovery of the cancer cells and their purity of isolation from samples.

University Employee; University Title; Relationship with Labyrinth Biotech Inc.

- Sunitha Nagrath; Associate Professor, Chemical Engineering; Partial Owner

Project #10

**Research Agreement between the University and Lassen Peak, Inc.
Reviewed by the UMOR Conflict of Interest Committee**

Project Information

Title: Radar Signal Processing on FPGA

U-M Project ID: 21-PAF04457

Direct Sponsor: Lassen Peak, Inc.

Principal Investigator/Department: Ehsan Afshari, Electrical Engineering and Computer Science – Electrical and Computer Engineering (EECS-ECE) Division

Project Duration: Four (4) Months

Funding Support: \$34,147

Purpose: The purpose of this project is to shorten imaging time by using field-programmable gate array (FPGA) hardware that is provided by the sponsor.

University Employee; University Title; Relationship with Lassen Peak, Inc.

- Ehsan Afshari; Professor, EECS – ECE Division; Partial Owner

Project #11

STTR Phase I Subcontract Agreement between the University and Mekanistic Therapeutics LLC Reviewed by the Medical School Conflict of Interest Board

Project Information

Title: Development of Novel Therapeutic Molecules for Treatment of Squamous Head and Neck Cancers

U-M Project ID: 21-PAF03989

Direct Sponsor: Mekanistic Therapeutics LLC

Prime Sponsor: National Institutes of Health

Principal Investigator/Department: Judith Leopold, Radiology

Project Duration: One (1) Year

Funding Support: \$119,050

Purpose: The purpose of this project is to provide preclinical proof of concept to support monotherapy development of a lead EGFR/PI3K inhibitor that is ideally suited to treat squamous head and neck cancers.

University Employee; University Title; Relationship with Mekanistic Therapeutics LLC

- Judith Leopold; Research Professor, Radiology; Partial Owner
- Christopher Whitehead; Chemist Staff Specialist, Radiology; Partial Owner

Project #12

Second Amendment to Research Agreement between the University and nanoMAG, LLC Reviewed by the Medical School Conflict of Interest Board

Project Information

Title: Bioabsorbable Magnesium Orthopaedic Spinal Implants

U-M Project ID: 21-PAF03770

Direct Sponsor: nanoMAG, LLC

Principal Investigator/Department: Kenneth Kozloff, Orthopaedic Surgery

Agreement Initiated: September 1, 2017

First Amendment Effective: September 1, 2018

Current Project Duration: Three (3) Years, Four (4) Months
Additional Time: Six (6) Months

Current Funding Support: \$39,986
Additional Support: \$5,228

Purpose: The purpose of this amendment to add additional funds and time so that Dr. Kozloff may continue to demonstrate the feasibility of using bioabsorbable magnesium alloys for spinal cage implants by characterizing a bioabsorbable magnesium alloy as an intervertebral body spinal fusion cage in a sheep cervical spinal model.

University Employee; University Title; Relationship with nanoMAG, LLC

- Steven Goldstein; Professor Emeritus, Orthopaedic Surgery; Board of Directors Member

Project #13

Research Agreement between the University and Patient-Centered Outcomes Research Institute Reviewed by the UMOR Conflict of Interest Committee

Project Information

Title: Pediatric Renovascular Hypertension: A pRVH PCOR Collaborative **U-M Project ID:** 21-PAF00031

Direct Sponsor: Patient-Centered Outcomes Research Institute (PCORI)

Principal Investigator/Department: Dawn Coleman, Vascular Surgery Section

Project Duration: Two (2) Years

Funding Support: \$249,768

Purpose: The purpose of this project is to: 1) Create a pRVH PCOR collaborative; 2) Prioritize PCOR and comparative effectiveness research around critical diagnostic and treatment decisions; 3) Conduct a pRVH symposium in 2022.

University Employee; University Title; Relationship with PCORI

- Christopher Friese; Professor, Nursing; Board of Directors Member

Project #14

Research Amendment between the University and Patient-Centered Outcomes Research Institute Reviewed by the UMOR Conflict of Interest Committee

Project Information

Title: Continued anticonvulsants after resolution of neonatal seizures: a patient-centered comparative effectiveness study (Statistics support)

U-M Project ID: 21-PAF04226

Direct Sponsor: Patient-Centered Outcomes Research Institute (PCORI)

Principal Investigator/Department: Renee Shellhaas, Pediatrics-Neurology

Agreement Initiated: July 1, 2016

Current Project Duration: Five (5) Years

Additional Time: N/A

Current Funding Support: \$2,876,265

Additional Funding: \$2,894

Purpose: The purpose of this amendment to add additional funds for a study statistician to work on multiple imputation, refining the propensity weighted analysis and instrumental variable analysis, graphical representation of the data, and written explanations of these methods. The overall objective of the research is to examine whether the duration of seizure treatment affects outcomes of 250 neonates with seizures.

University Employee; University Title; Relationship with PCORI

- Christopher Friese; Professor, Nursing; Board of Directors Member

Project #15

**STTR Phase II Subcontract Agreement between the University and Prehab Technologies, LLC
Reviewed by the Medical School Conflict of Interest Board**

Project Information

Title: A Fully-Automated Endoscopic Mayo Scoring Technology

U-M Project ID: 21-PAF03487

Direct Sponsor: Prehab Technologies, LLC dba Prenovo

Prime Sponsor: National Science Foundation

Principal Investigator/Department: Kayvan Najarian, Computational Medicine and Bioinformatics

Project Duration: Two (2) Years

Funding Support: \$406,768

Purpose: The purpose of this project is to evaluate the performance of an improved informative frame classification, better estimated camera locations, and to differentiate bleeding due to disease and that induced by biopsy. The revised automated scoring system's performance will be validated against a heterogeneous dataset from multiple clinical providers.

University Employee; University Title; Relationship with Prehab Technologies, LLC

- Stewart Wang; Professor, Director, Surgery; Partial Owner

Project #16

**Second Amendment to Research Agreement between the University and Sarcoma Alliance for Research through Collaboration
Reviewed by the Medical School Conflict of Interest Board**

Project Information

Title: LMS Project

U-M Project ID: 21-PAF03875

Direct Sponsor: Sarcoma Alliance for Research through Collaboration (SARC)

Principal Investigator/Department: Laurence Baker, Internal Medicine – Hematology/Oncology

Agreement Originally Approved by the Regents: December 6, 2018

First Amendment Approved by the Regents: December 3, 2020

Current Project Duration: Two (2) Years, Four (4) Months
Additional Time: Eight (8) Months

Current Funding Support: \$275,002
Additional Support: \$93,596

Purpose: The purpose of this amendment is to add additional funds and time for the continued support of Dr. Baker's work with SARC to organize investigators focused on researching strategic LMS vulnerabilities and developing effective therapies.

University Employee; University Title; Relationship with SARC

- Denise Reinke; Nurse Practitioner, UMH Cancer Center; President and Chief Executive Officer

Project #17

**STTR Phase I Subcontract Agreement between the University and Tulip Make Me Move Desk, LLC
Reviewed by the Medical School Conflict of Interest Board**

Project Information

Title: Development of the Multifunctional Rehabilitation Standing Device for older adults with motoric cognitive risk syndrome

U-M Project ID: 21-PAF04065

Direct Sponsor: Tulip Make Me Move Desk, LLC

Prime Sponsor: National Institutes of Health

Principal Investigator/Department: Nicolaas Bohnen, Radiology

Project Duration: One (1) year

Funding Support: \$167,270

Purpose: The purpose of this project is to develop a novel “Dynamic Standing Desk” prototype that allows for multidirectional stepping movements to improve mobility and prevent falls in older subjects with motoric cognitive risk syndrome.

University Employee; University Title; Relationship with Tulip Make Me Move Desk, LLC

- Nicolaas Bohnen; Professor, Radiology; Partial Owner