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,

Arthur Lupia

Interim Vice President for Research and Innovation

September 2024

Attachment A

Project #1

Other Sponsored Activity Agreement between the University and Digital Blue Corporation Reviewed by the UMOR Conflict of Interest Review Committee		
Project Information		
U-M Project ID: 24-PAF07346		
Prime Sponsor: MRA Systems, LLC dba Middle River Aerostructure Systems (MRAS)		
Principal Investigator/Department: Royan D'Mello, Aerospace Engineering		
Funding Support: \$24,830		

Purpose: The purpose of this activity is to perform the following testing for Digital Blue Corporation: 1) tests for characterizing the unidirectional tape material; 2) tests for characterizing the fabric material.

University Employee; University Title; Relationship with Digital Blue Corporation

- Royan D'Mello; Assistant Research Scientist, Aerospace Engineering; Partial Owner
- Anthony Waas; Professor Emeritus, Aerospace Engineering; Partial Owner

Project #2

STTR Phase I Subcontract Agreement between the University and Intero Biosystems Inc. Reviewed by the Medical School Conflict of Interest Board		
Project Information		
Title: A novel multi-lineage human intestinal organoid screening platform for drug discovery and pre-clinical testing	U-M Project ID: 25-PAF00805	
Direct Sponsor: Intero Biosystems Inc.	Prime Sponsor: National Institutes of Health	
Principal Investigator/Department: Jason Spence, Internal Medicine – Gastroenterology		
Project Duration: One (1) Year	Funding Support: \$110,863	

Purpose: The purpose of this project is to develop and commercialize the first stem cell derived HIO model which mimics the structure and function of the human intestine and is amenable to higher throughput screening.

University Employee; University Title; Relationship with Intero Biosystems Inc.

- Jason Spence; Professor, Gastrointestinal Sciences; Partial Owner
- Charlie Childs; Research Fellow, Internal Medicine Gastroenterology; Partial Owner

Other Sponsored Activity Agreement between the University and Mekanistic Therapeutics, Inc. Reviewed by the Medical School Conflict of Interest Board

Project Information

Title: MEKanistic Fee-For-Service: Evaluation of In Vivo Antitumor

Activity of MTX-531

U-M Project ID: 24-PAF09024

Direct Sponsor: Mekanistic Therapeutics, Inc.

Principal Investigator/Department: Judith Leopold, Radiology

Project Duration: Nine (9) Months Funding Support: \$220,563

Purpose: The purpose of this activity is to extend in vivo evaluation of MTX-531 to include a broad spectrum of non head and neck tumor models.

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

- Judith Leopold; Research Professor, Radiology; Partial Owner
- Mary Stewart; Contract and Grant Specialist, Radiology; Partial Owner

Project #4

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

Project Information

Title: Control of Lung Cancer and Metastases by a Mg Alloy U-M Project ID: 25-PAF00826

Direct Sponsor: nanoMAG, LLC **Prime:** National Institutes of Health

Principal Investigator/Department: Claudia Loebel, Materials Science and Engineering

Project Duration: One (1) Year Funding Support: \$150,000

Purpose: The purpose of this project is to perform in vitro and in vivo testing of BioMg 250 wires, using precision cut lung slices (PCLS) and mouse models for insertion and lung tissue analysis, and observing human A549 cell response to BioMg 250 wires for nanoMAG, LLC.

University Employee; University Title; Relationship with nanoMAG, LLC

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

SBIR Phase II Subcontract Agreement between the University and PhotoSonoX LLC Reviewed by the Medical School Conflict of Interest Board

Project Information

Title: Photo-mediated Ultrasound Therapy for Treatment of Cutaneous

U-M Project ID: 25-PAF01146

Vascular Malformations

Direct Sponsor: PhotoSonoX LLC

Prime: National Institutes of Health

Principal Investigator/Department: Xueding Wang, MM Biomedical Engineering

Project Duration: Three (3) Years

Funding Support: \$998,981

Purpose: The purpose of this project is to 1) develop a clinically ready β -prototype PUT system for PWS treatment; 2) optimize the β -prototype device in chicken wattle model; and 3) perform a phase 1 human clinical trial to evaluate the operation procedure, safety, and efficacy of the β -prototype PUT system.

University Employee; University Title; Relationship with PhotoSonoX LLC

- Yannis Paulus; Professor, Ophthalmology & Visual Science; Partial Owner
- Xueding Wang; Professor, Biomedical Engineering; Partial Owner

Project #6

Sixth Amendment to Other Sponsored Activity Agreement between the University and Rappta Therapeutics Oy

Reviewed by the Medical School Conflict of Interest Board

Project Information

Title: Testing of small molecule PP2A activators in cellular and in vivo systems

U-M Project ID: 24-PAF06616

Direct Sponsor: Rappta Therapeutics Oy

Principal Investigator/Department: Goutham Narla, Internal Medicine - Genetic Medicine

Agreement Originally Approved by the Regents: May 21, 2020 First Amendment Approved by the Regents: December 9, 2021

Second Amendment (not funded) Approved by the Regents: July 21, 2022

Third (not funded) and Fourth Amendments Approved by the Regents: March 23, 2023

Fifth Amendment Approved by the Regents: February 15, 2024

Current Project Duration: Sixty-Four (64) Months

Current Funding Support: \$3,850,000 Additional Funding Support: \$1,500,000

Additional Project Duration: One (1) Year

10 1 4 D N 1

Purpose: The purpose of this amendment is to add additional time and funds so that Dr. Narla may continue to test the effects of a series of small molecule activators of PP2A on cancer cell lines.

University Employee; University Title; Relationship with Rappta Therapeutics Oy

• Goutham Narla; Professor, Internal Medicine – Genetic Medicine; Partial Owner

Fifth Amendment to Other Sponsored Activity Agreement between the University and Rappta Therapeutics Oy

Reviewed by the Medical School Conflict of Interest Board

Project Information

Title: Characterizing role of novel PP2A activators in human cancer

U-M Project ID: 24-PAF06617

Direct Sponsor: Rappta Therapeutics Oy

Principal Investigator/Department: Goutham Narla, Internal Medicine - Genetic Medicine

Agreement Originally Approved by the Regents: October 21, 2021

First Amendment Approved by the Regents: July 21, 2022 Second Amendment Approved by the Regents: March 23, 2023 Third Amendment Approved by the Regents: February 15, 2024 Fourth Amendment Approved by the Regents: July 18, 2024

Current Project Duration: Four (4) Years, Four (4) Months **Additional Project Duration:** One (1) Year

Current Funding Support: \$4,600,000 Additional Funding Support: \$2,000,000

Purpose: The purpose of this amendment is to add additional time and funds so that Dr. Narla may continue to test the effects of a series of small molecule activators of PP2A on a series of cancer cell lines.

University Employee; University Title; Relationship with Rappta Therapeutics Oy

• Goutham Narla; Professor, Internal Medicine – Genetic Medicine; Partial Owner

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: STTR Ph I A0 Pongmala/Baylin: Development of elastic standing-enhanced dynamic standing desk (ESEDESK) to manage metabolic risk in overweight office workers	U-M Project ID: 25-PAF01110		
Direct Sponsor: Tulip Make Me Move Desk, LLC	Prime Sponsor: National Institutes of Health		
Principal Investigator/Department: Fay Pongmala, Radiology			
Project Duration: One (1) Year	Funding Support: \$208,023		

Purpose: The purpose of this project is to test the hypothesis that use of the ESEDESK can further improve on the metabolic effects observed with the dynamic standing desk (DSK) alone by an estimated effect size of 40% incremental improvement based on a combination of improved standing tolerance and increased muscular metabolic effects.

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

Nicolaas Bohnen; Professor, Radiology; Partial Owner

Project #9

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

Reviewed by the Medical School Conflict of Interest Board		
Project Information		
Title: STTR Phase II A1 Pongmala: In-Home Multifunctional Rehabilitation Standing and Stepping Device for People with Parkinson's disease	U-M Project ID: 25-PAF01114	
Direct Sponsor: Tulip Make Me Move Desk, LLC	Prime Sponsor: National Institutes of Health	
Principal Investigator/Department: Fay Pongmala, Radiology		
Project Duration: Three (3) Years	Funding Support: \$1,797,885	
Purpose. The purpose of this project is for a 12 week randomized controlled single blinded clinical trial of in		

Purpose: The purpose of this project is for a 12-week randomized controlled, single blinded clinical trial of inhome promotion of low-intensity physical activity while decreasing sedentary behavior using a Multifunctional Rehabilitation Standing and Stepping Device in persons with Parkinson's Disease and Postural Instability and Gait Difficulty features.

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

• Nicolaas Bohnen; Professor, Radiology; Partial Owner