

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

December 2021

## Attachment A

### Project #1

<b>Third Amendment to Research Agreement between the University and Eli Lilly and Company Reviewed by the Medical School Conflict of Interest Board</b>	
<b><u>Project Information</u></b>	
<b>Title:</b> The Renal Pre-Competitive Consortium (RPC2) - Eli Lilly (2022-2023)	<b>U-M Project ID:</b> 22-PAF02100
<b>Direct Sponsor:</b> Eli Lilly and Company	
<b>Principal Investigator/Department:</b> Matthias Kretzler, Internal Medicine-Nephrology	
<b>Agreement Originally Approved by the Regents:</b> October 15, 2015	
<b>Current Project Duration:</b> Six (6) Years, Three (3) Months <b>Additional Time:</b> Two (2) Years	<b>Current Funding Support:</b> \$946,041 <b>Additional Funding Support:</b> \$1,187,010
<b>Purpose:</b> The purpose of this amendment is to add funds and time so that Dr. Kretzler may continue efforts in the consortium to facilitate pre-competitive renal research by providing access and analysis of a number of large datasets associated with renal disease to better understand key pathways and identify potential targets for the development of diagnostic and therapeutic compounds.	
<b><u>University Employee; University Title; Relationship with Eli Lilly and Company</u></b> <ul style="list-style-type: none"><li>• Marschall Runge; Executive Vice President for Medical Affairs, Dean of the Medical School; Board of Directors Member</li></ul>	

### Project #2

<b>Research Agreement between the University and Eli Lilly and Company Reviewed by the Medical School Conflict of Interest Board</b>	
<b><u>Project Information</u></b>	
<b>Title:</b> Novel Colloidal Interaction Methods for Identifying Biologics with Drug-Like Solution Properties	<b>U-M Project ID:</b> 22-PAF03042
<b>Direct Sponsor:</b> Eli Lilly and Company	
<b>Principal Investigator/Department:</b> Peter Tessier, Pharmaceutical Sciences	
<b>Project Duration:</b> Two (2) Years	<b>Funding Support:</b> \$343,356
<b>Purpose:</b> The purpose of this project is to evaluate, adapt and optimize a novel assay, namely charge-stabilized self-interaction nanoparticle spectroscopy (CS-SINS), for evaluating mAb and non-mAb self-association at ultra-dilute protein concentrations (0.001-0.01 mg/mL) in a range of standard formulation conditions, and evaluate the ability of CS-SINS measurements to identify mAbs and non-mAbs with low viscosity and low opalescence in concentrated formulations (>100 mg/mL).	
<b><u>University Employee; University Title; Relationship with Eli Lilly and Company</u></b> <ul style="list-style-type: none"><li>• Marschall Runge; Executive Vice President for Medical Affairs, Dean of the Medical School; Board of Directors Member</li></ul>	

### Project #3

**SBIR Phase II Subcontract Agreement between the University and FibrosIX, Inc.  
Reviewed by the UMOR Conflict of Interest Review Committee**

#### Project Information

**Title:** Pre-clinical efficacy and safety of a pirin inhibitor for mitigating bleomycin- and radiation-induced lung fibrosis Phase II

**U-M Project ID:** 22-PAF00499

**Direct Sponsor:** FibrosIX, Inc.

**Prime Sponsor:** National Institutes of Health

**Principal Investigator/Department:** Dipankar Ray, Radiology Oncology

**Project Duration:** Two (2) Years

**Funding Support:** \$448,026

**Purpose:** The purpose of project is to incorporate FBX642 as a standard component of all bleomycin chemotherapy and thoracic radiotherapy regimens, allowing oncologists to administer the full treatment regimen required to patients, resulting in reduced morbidity and mortality in cancer survivors.

#### University Employee; University Title; Relationship with FibrosIX, Inc.

- Scott Larsen; Research Professor, Medicinal Chemistry; Partial Owner

### Project #4

**STTR Phase II Subcontract Agreement between the University and H3D, Inc.  
Reviewed by the UMOR Conflict of Interest Review Committee**

#### Project Information

**Title:** General Purpose Radiation Detector Front End and Digital Processor - STTR II

**U-M Project ID:** 22-PAF02974

**Direct Sponsor:** H3D, Inc.

**Prime Sponsor:** Department of Defense - Army

**Principal Investigator/Department:** Yuefeng Zhu, Nuclear Engineering & Radiological Sciences (NERS)

**Project Duration:** Two (2) Years

**Funding Support:** \$295,045

**Purpose:** The University will build a general-purpose integrated circuit (GPIC) data acquisition (DAQ) system, the digital data processing system and construct a user interface to operate the systems.

#### University Employee; University Title; Relationship with H3D, Inc.

- Zhong He; Professor, NERS; Partial Owner
- Yuefeng Zhu; Associate Research Scientist, NERS; Partial Owner

### Project #5

**Other Sponsored Activity Agreement between the University and HiPer Fiber, LLC  
Reviewed by the UMOR Conflict of Interest Review Committee**

#### Project Information

**Title:** HiPer Fiber Performance Testing

**U-M Project ID:** 22-PAF02880

**Direct Sponsor:** HiPer Fiber, LLC

**Principal Investigator/Department:** Jason McCormick, Civil & Environmental Engineering

**Project Duration:** Nine (9) Months

**Funding Support:** \$6,100

**Purpose:** The purpose of this activity is to conduct a series of pullout, compression, direct tensile and flexural tests on specimens from six different mix designs in order to determine the capacity of different mix designs and fiber volume fractions.

#### University Employee; University Title; Relationship with HiPer Fiber, LLC

- Sherif El-Tawil; Professor, Civil & Environmental Engineering; Partial Owner

### Project #6

**STTR Phase I Subcontract Agreement between the University and Mitovation, Inc.  
Reviewed by the Medical School Conflict of Interest Board**

#### Project Information

**Title:** Neuroprotective Device for Treating Brain Injury  
Following Cardiac Arrest

**U-M Project ID:** 22-PAF02021

**Direct Sponsor:** Mitovation, Inc.

**Prime Sponsor:** National Institutes of Health

**Principal Investigator/Department:** Robert Neumar, Emergency Medicine Research

**Project Duration:** Five (5) Years

**Funding Support:** \$452,412

**Purpose:** The purpose of project is to produce a clinical Light Utilizing COX-Inhibitory Device to provide treatment for infant brain injury due to cardiac arrest.

#### University Employee; University Title; Relationship with Mitovation, Inc.

- Thomas Sanderson; Associate Professor, Emergency Medicine; Partial Owner

### Project #7

**Phase I Subcontract Agreement between the University and MONDE Wireless Inc.  
Reviewed by the UMOR Conflict of Interest Review Committee**

#### Project Information

**Title:** Thermally Managed N-polar GaN FETs

**U-M Project ID:** 21-PAF06383

**Direct Sponsor:** MONDE Wireless, Inc.

**Prime Sponsor:** Department of Defense - Navy

**Principal Investigator/Department:** Elaheh Ahmadi, Electrical Engineering and Computer Science – Electrical and Computer Engineering (EECS-ECE) Division

**Project Duration:** Two (2) Years, Seven (7) Months

**Funding Support:** \$8,000

**Purpose:** The University will be responsible for performing ohmic contact regrowth.

#### University Employee; University Title; Relationship with MONDE Wireless Inc.

- Elaheh Ahmadi; Assistant Professor, EECS-ECE Division; Partial Owner

### Project #8

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

#### Project Information

**Title:** Design and Methodological Development for a Patient Preference SMART

**U-M Project ID:** 21-PAF03651

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

**Principal Investigator/Department:** Kelley Kidwell, Biostatistics

**Project Duration:** Three (3) Years, Three (3) Months

**Funding Support:** \$998,998

**Purpose:** The purpose of this project is to incorporate the idea of a partially randomized patient preference (PRPP) design into sequential, multiple assignment randomized trials (SMARTs) that will allow participants with a preference to be assigned to the treatment they prefer, and those without a preference to be randomized to a treatment.

#### University Employee; University Title; Relationship with PCORI

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

### Project #9

**Other Sponsored Activity Agreement between the University and Patient-Centered Outcomes Research Institute**  
**Reviewed by the UMOR Conflict of Interest Review Committee**

#### Project Information

**Title:** Developing a Research Roadmap for the Pediatric Surgical Oncology Research Collaborative

**U-M Project ID:** 21-PAF08689

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

**Principal Investigator/Department:** Peter Ehrlich, Pediatric Surgery

**Project Duration:** One (1) Year

**Funding Support:** \$100,000

**Purpose:** The purpose of this activity is to enable parents of patients with cancer to be engaged in planning new research on surgical outcomes and comparative effectiveness, develop a patient-centered model for this research, and develop a roadmap for future research based on patient-centered priorities.

#### University Employee; University Title; Relationship with PCORI

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

### Project #10

**Amendment to an Other Sponsored Activity between the University and Rappta Therapeutics Oy**  
**Reviewed by the Medical School Conflict of Interest Board**

#### Project Information

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

**U-M Project ID:** 22-PAF02403

**Direct Sponsor:** Rappta Therapeutics Oy

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

**Agreement Originally Approved by the Regents:** May 21, 2020

**Current Project Duration:** Nineteen (19) Months  
**Additional Time:** One (1) Year

**Current Funding Support:** \$1,500,000  
**Additional Funding Support:** \$750,000

**Purpose:** The purpose of this amendment is to add funds and time so that Dr. Narla may continue to test the cellular 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