

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 "Arthur Lupia". The signature is fluid and cursive, with the first name "Arthur" and last name "Lupia" clearly distinguishable.

Arthur Lupia  
Interim Vice President for Research and Innovation

June 2024

**Attachment A**

**Project #1**

<b>SBIR Phase I Subcontract Agreement between the University and Amphionic LLC Reviewed by the UMOR Conflict of Interest Review Committee</b>	
<b><u>Project Information</u></b>	
<b>Title:</b> DARPA ARS Phase I - Lightweight enhanced-attenuation shielding for high-energy gamma-rays based on nanostructured composite materials	<b>U-M Project ID:</b> 24-PAF04671
<b>Direct Sponsor:</b> Amphionic LLC	<b>Prime Sponsor:</b> Department of Defense Advanced Research Projects Agency
<b>Principal Investigator/Department:</b> Mark Hammig, Nuclear Engineering and Radiological Sciences	
<b>Project Period:</b> March 15, 2023 - November 14, 2023	<b>Funding Support:</b> \$37,500
<b>Purpose:</b> The purpose of this project was to develop and demonstrate inexpensive, lightweight, compact, and potentially flexible radiation shielding for high-energy gamma-rays, which will ensure the survivability of personnel and equipment in high-dose environments such as in outer space or in nuclear detonations.	
<b><u>University Employee; University Title; Relationship with Amphionic LLC</u></b>	
<ul style="list-style-type: none"><li>● Mark Hammig; Research Scientist, Nuclear Engineering and Radiological Sciences; Partial Owner</li><li>● Suneel Joglekar; Research Fellow, Nuclear Engineering and Radiological Sciences; CEO</li><li>● Drew Vecchio; Research Fellow, Nuclear Engineering and Radiological Sciences; Vice President of Engineered Materials</li></ul>	
<b>Special Circumstances:</b> The University of Michigan work on this subcontract has already been completed, but no formal agreement between the University and Amphionic LLC is in place yet and no COI management has been established. The delay in processing this project was due to staff turnover and a change in the company negotiator.	

## Project #2

### SBIR Phase I Subcontract Agreement between the University and Amphionic LLC Reviewed by the UMOR Conflict of Interest Review Committee

#### Project Information

**Title:** NASA Phase I - Lightweight ultra-strong flexible power cables from metallic nanoparticles and aramid nanofibers

**U-M Project ID:** 24-PAF04701

**Direct Sponsor:** Amphionic LLC

**Prime:** National Aeronautics and Space Administration

**Principal Investigator/Department:** Mark Hammig, Nuclear Engineering and Radiological Sciences

**Project Period:** November 1, 2023 – February 2, 2024

**Funding Support:** \$44,126

**Purpose:** The purpose of this project was to develop multi-functional electrical cabling and electrical interconnects for spacecraft and aircraft that delivers high conductivity and power-handling capability with at least an order of magnitude less mass (per unit length), a weight reduction that frees up precious aircraft and space resources, and can increase the scientific and operational capabilities of the spacecraft.

#### University Employee; University Title; Relationship with Amphionic LLC

- Mark Hammig; Research Scientist, Nuclear Engineering and Radiological Sciences; Partial Owner
- Suneel Joglekar; Research Fellow, Nuclear Engineering and Radiological Sciences; CEO
- Drew Vecchio; Research Fellow, Nuclear Engineering and Radiological Sciences; Vice President of Engineered Materials

**Special Circumstances:** The University of Michigan work on this subcontract has already been completed, but no formal agreement between the University and Amphionic LLC is in place yet and no COI management has been established. The delay in processing this project was due to staff turnover and a change in the company negotiator.

### Project #3

**Amendment to Subcontract Agreement between the University and Dermira, Inc. (acquired by Eli Lilly and Company)**  
**Reviewed by the Medical School Conflict of Interest Board**

#### Project Information

**Title:** 5634-Gudjonsson DERM 792 | Eli Lilly | Eli Lilly and Almirall Lebrikizumab Mechanistic Study

**U-M Project ID:** 24-PAF04207

**Direct Sponsor:** Dermira, Inc.

**Prime Sponsor:** Almirall Prodesfarma, S.A.

**Principal Investigator/Department:** Johann Gudjonsson, Dermatology

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

**Current Funding Support:** \$6,540,193  
**Additional Funding Support:** \$1,382,027

**Purpose:** The purpose of this amendment is to add funding support established during contract negotiations that is necessary for Dr. Gudjonsson to map out the molecular response to lebrikizumab and determine if effective long-term neutralization of IL-13 in treated atopic dermatitis (AD) skin leads to long-term normalization of immune homeostasis in resolved AD skin lesions, normalization of non-lesional AD skin towards that of healthy (non-AD) subjects, and resolution of epigenetic changes in stromal cells (keratinocytes/fibroblasts/endothelial cells/mast cells).

#### 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 #4

<b>SBIR Phase II Subcontract Agreement between the University and EVOQ Therapeutics, Inc. Reviewed by the UMOR Conflict of Interest Review Committee</b>	
<b><u>Project Information</u></b>	
<b>Title:</b> Novel Immunotherapy Against MOG Antibody Disease	<b>U-M Project ID:</b> 24-PAF04014
<b>Direct Sponsor:</b> EVOQ Therapeutics, Inc.	<b>Prime Sponsor:</b> National Institutes of Health
<b>Principal Investigator/Department:</b> James Moon, Pharmaceutical Sciences	
<b>Project Duration:</b> Two (2) Years	<b>Funding Support:</b> \$200,000
<b>Purpose:</b> The purpose of this project is to evaluate the efficacy of nanodiscs against myelin oligodendrocyte glycoprotein (MOG) antibody disease (MOGAD) in murine models and perform immunological assessments.	
<b><u>University Employee; University Title; Relationship with EVOQ Therapeutics, Inc.</u></b>	
<ul style="list-style-type: none"><li>● James Moon; Professor, Pharmaceutical Sciences; Partial Owner</li><li>● Anna Schwendeman; Professor, Pharmaceutical Sciences; Partial Owner</li></ul>	

#### Project #5

<b>SBIR Phase II Subcontract Agreement between the University and Inspire Rx LLC Reviewed by the Medical School Conflict of Interest Board</b>	
<b><u>Project Information</u></b>	
<b>Title:</b> Personal Respiratory Isolation System for Safe Transport and Treatment of Patients with Highly Transmissible Infectious Diseases	<b>U-M Project ID:</b> 24-PAF01010
<b>Direct Sponsor:</b> Inspire Rx LLC	<b>Prime Sponsor:</b> National Institutes of Health
<b>Principal Investigator/Department:</b> Nathaniel Hunt, Emergency Medicine	
<b>Project Duration:</b> One (1) Year	<b>Funding Support:</b> \$151,444
<b>Purpose:</b> The purpose of this project is to refine, test and submit for FDA approval a compact, portable, self-contained, personal negative pressure environment (using AerosolVE BioHelmet) to prevent spread of aerosolized pathogens from patients to frontline healthcare workers while enabling non-invasive oxygen therapies on patients with any respiratory disease such as COVID-19, tuberculosis, SARS, etc.	
<b><u>University Employee; University Title; Relationship with Inspire Rx LLC</u></b>	
<ul style="list-style-type: none"><li>● Benjamin Bassin; Clinical Associate Professor, Emergency Medicine; Chief Medical Officer</li><li>● Kevin Ward; Professor, Emergency Medicine; Partial Owner</li></ul>	

### Project #6

<b>Other Sponsored Activity Agreement between the University and MDI Therapeutics, Inc. Reviewed by the Medical School Conflict of Interest Board</b>	
<b><u>Project Information</u></b>	
<b>Title:</b> MDI MedChem Studies – Phase 2	<b>U-M Project ID:</b> 24-PAF06752
<b>Direct Sponsor:</b> MDI Therapeutics, Inc.	
<b>Principal Investigator/Department:</b> Daniel Lawrence, Internal Medicine - Cardiology	
<b>Project Duration:</b> One (1) Year	<b>Funding Support:</b> \$42,816
<b>Purpose:</b> The purpose of this activity is to analyze novel compounds for plasminogen activator inhibitor-1 (PAI-1) inhibitory activity in vitro, and confirm top hits in vivo in PAI-1 transgenic mice.	
<b><u>University Employee; University Title; Relationship with MDI Therapeutics, Inc.</u></b>	
<ul style="list-style-type: none"><li>● Daniel Lawrence; Professor, Internal Medicine-Cardiology; Partial Owner</li><li>● Enming Su; Associate Research Scientist, Internal Medicine-Cardiology; Partial Owner</li></ul>	

### Project #7

<b>Other Sponsored Activity Agreement between the University and PathwaysGI, Inc. (formerly known as PathwaysGI, LLC) Reviewed by the Medical School Conflict of Interest Board</b>	
<b><u>Project Information</u></b>	
<b>Title:</b> PathwaysGI, Inc. – DUA for Data Export External Company	<b>U-M Project ID:</b> 24-PAF00653
<b>Direct Sponsor:</b> PathwaysGI, Inc.	
<b>Principal Investigator/Department:</b> Ryan Stidham, Internal Medicine-Gastroenterology	
<b>Project Duration:</b> Four (4) Years	<b>Funding Support:</b> \$50,000
<b>Purpose:</b> The purpose of this activity is to formalize outgoing data usage rights for University of Michigan data being used by PathwaysGI, Inc. for software validation purposes with the goal of being able to better assess inflammatory bowel disease (IBD) patients.	
<b><u>University Employee; University Title; Relationship with PathwaysGI, Inc.</u></b>	
<ul style="list-style-type: none"><li>● Kayvan Najarian; Professor, Computational Medicine and Bioinformatics; Partial Owner</li><li>● Ryan Stidham; Associate Professor, Internal Medicine–Gastroenterology; Partial Owner</li></ul>	

## Project #8

### Second Amendment to Research Agreement between the University and Phenomics Health Inc. Reviewed by the Medical School Conflict of Interest Board

#### Project Information

**Title:** Feasibility determination of retrospective clinical validation and extension of pharmacogenomics assays using patient-specific data and analytics

**U-M Project ID:** 22-PAF03766

**Direct Sponsor:** Phenomics Health Inc.

**Principal Investigator/Department:** Brian Athey, Computational Medicine and Bioinformatics

**Agreement Originally Approved by the Regents:** February 17, 2022

**First Amendment Approved by the Regents:** October 17, 2023

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

**Current Funding Support:** \$916,716

**Additional Funding Support:** \$6,240

**Purpose:** The purpose of this amendment is to add funding support established during contract negotiations that is necessary for Dr. Athey to lay the groundwork and build the necessary research infrastructure to create, demonstrate and evaluate a new first-generation and then second-generation neuropsychiatric pharmacogenomics (PGx) diagnostic assay for patients suffering from Major Depressive Disorder (MDD) and Treatment Resistant Depression (TRD), Generalize Anxiety Disorder (GAD), and Substance Use Disorder (SUD).

#### University Employee; University Title; Relationship with Phenomics Health Inc.

- Brian Athey; Professor, Computational Medicine and Bioinformatics; Partial Owner