

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

May 2023

Attachment A

Project #1

Second Amendment to an Other Sponsored Activity Agreement between the University and EVOQ Therapeutics, Inc. Reviewed by the UMOR Conflict of Interest Review Committee	
<u>Project Information</u>	
Title: EVOQ General Service Agreement 3 - Amend 2	U-M Project ID: 23-PAF05813
Direct Sponsor: EVOQ Therapeutics, Inc.	
Principal Investigator/Department: James Moon, Pharmaceutical Sciences	
Agreement Originally Approved by the Regents: March 25, 2021 First Amendment Approved by the Regents: March 24, 2022	
Current Project Duration: Two (2) Years Additional Time: Two (2) Years	Current Funding Support: \$600,000 Additional Funding Support: \$900,000
Purpose: The purpose of this amendment is to add additional time and funds so that Dr. Moon may continue to produce categories of nanodiscs, and characterize and evaluate them in mice for immunological outcomes.	
<u>University Employee; University Title; Relationship with EVOQ Therapeutics, Inc.</u>	
<ul style="list-style-type: none">● James Moon; Professor, Pharmaceutical Sciences; Partial Owner● Anna Schwendeman; Professor, Pharmaceutical Sciences; Partial Owner	

Project #2

STTR Phase I Subcontract Agreement between the University and GeneToBe Inc. (formerly known as GeneToBe, LLC) Reviewed by the Medical School Conflict of Interest Board	
<u>Project Information</u>	
Title: Developing novel Type 1 CRISPR tools for gene editing therapy STTR Phase I	U-M Project ID: 23-PAF05752
Direct Sponsor: GeneToBe Inc.	Prime Sponsor: National Institutes of Health
Principal Investigator/Department: Zhonggang Hou, Biological Chemistry	
Project Duration: One (1) Year	Funding Support: \$120,000
Purpose: The purpose of this project is to carry out gene editing experiments developing novel type I CRISPR based tools for gene therapy and the design and testing of T1-CRISPR tools for correcting disease-causing mutations.	
<u>University Employee; University Title; Relationship with GeneToBe Inc.</u>	
<ul style="list-style-type: none">• Yuqing Chen; Professor, Cardiovascular Medicine; Partial Owner• Jie Xu, Research Associate Professor, Internal Medicine-Cardiology; Partial Owner	

Project #3

STTR Phase I Subcontract Agreement between the University and GrayRain, LLC Reviewed by the UMOR Conflict of Interest Review Committee	
<u>Project Information</u>	
Title: A novel data de-identification platform for structured and unstructured biomedical data	U-M Project ID: 23-PAF00261
Direct Sponsor: GrayRain, LLC	Prime Sponsor: National Institutes of Health
Principal Investigator/Department: Ivo Dinov, School of Nursing	
Project Duration: One (1) Year	Funding Support: \$176,494
Purpose: The purpose of this project is to establish feasibility of GrayRain LLC's technology to accurately and efficiently (re: scalability) deidentify and share large-scale complex electronic health record data repositories with a controlled risk of disclosing protected or personal health information.	
<u>University Employee; University Title; Relationship with GrayRain, LLC</u>	
<ul style="list-style-type: none">• Ivo Dinov; Professor, Nursing; Partial Owner• Simeone Marino; Research Computer Specialist, Nursing; Partial Owner	

Project #4

**SBIR Phase I Subcontract Agreement between the University and ImBio Inc. (formerly known as ImBio, LLC)
Reviewed by the Medical School Conflict of Interest Board**

Project Information

Title: Galban/Matuszak/IMBIO (Hatt) SBIR Ph I-A01:
Integrated CT-Based Software Application for Improved
Pulmonary Assessment During Lung Cancer Therapy

U-M Project ID: 23-PAF01073

Direct Sponsor: ImBio Inc.

Prime Sponsor: National Institutes of Health

Principal Investigator/Department: Craig Galban, Radiology

Project Duration: One (1) Year

Funding Support: \$90,435

Purpose: The purpose of this project is to develop and commercialize a CT-based imaging readout to assess pulmonary co-morbidities and improve radiation therapy treatment planning, which will mitigate potential pulmonary complications associated with radiation therapy.

University Employee; University Title; Relationship with ImBio Inc.

- Alnawaz Rehemtulla; Professor, Radiation Oncology; Partial Owner
- Brian Ross; Professor, Radiology; Partial Owner

Project #5

SBIR Phase II Subcontract Agreement between the University and Inspire Rx LLC Reviewed by the Medical School Conflict of Interest Board	
<u>Project Information</u>	
Title: Personal Respiratory Isolation System for Safe Transport and Treatment of Patients with Highly Transmissible Infectious Diseases (Hunt/Bassin sub fr Inspire Rx)	U-M Project ID: 23-PAF05916
Direct Sponsor: Inspire Rx LLC	Prime Sponsor: National Institutes of Health
Principal Investigator/Department: Nathaniel Hunt, Emergency Medicine	
Project Duration: One (1) Year	Funding Support: \$151,445
Purpose: The purpose of this project is to refine, test and submit for FDA approval a compact, portable, self-contained, personal negative pressure environment 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.	
<u>University Employee; University Title; Relationship with Inspire Rx LLC</u>	
<ul style="list-style-type: none">● Benjamin Bassin; Clinical Associate Professor, Emergency Medicine; Chief Medical Officer● Kevin Ward; Professor, Emergency Medicine; Partial Owner	

Project #6

Research Agreement between the University and NS Nanotech Inc. Reviewed by the UMOR Conflict of Interest Review Committee	
<u>Project Information</u>	
Title: High Efficiency InGaN Nanowire Red Micro-LEDs	U-M Project ID: 23-PAF04968
Direct Sponsor: NS Nanotech Inc.	
Principal Investigator/Department: Zetian Mi, Electrical Engineering and Computer Science – Electrical and Computer Engineering (EECS – ECE) Division	
Project Duration: One (1) Year	Funding Support: \$500,000
Purpose: The purpose of this project is to further develop high efficiency InGaN nanowire-based micro-LEDs operating in the red wavelengths (> 620 nm) with subpixel $\leq 1 \times 1 \mu\text{m}^2$ and EQE $> 10\%$.	
<u>University Employee; University Title; Relationship with NS Nanotech Inc.</u>	
<ul style="list-style-type: none">● Zetian Mi; Professor, EECS-ECE Division; Partial Owner	

Project #7

Research Agreement between the University and ONL Therapeutics, Inc. Reviewed by the Medical School Conflict of Interest Board	
<u>Project Information</u>	
Title: A Phase 2, Randomized, Sham-Controlled, Single-Masked, Dose-Ranging, Multi-Center Study to Assess the Safety and Efficacy of Intravitreal ONL1204 Ophthalmic Solution in Subjects with Macula-off Rhegmatogenous Retinal Detachment	U-M Project ID: 23-PAF05164
Direct Sponsor: ONL Therapeutics, Inc.	
Principal Investigator/Department: Thomas Wubben, Ophthalmology and Visual Sciences	
Project Duration: Two (2) Years	Funding Support: \$178,149
Purpose: The purpose of this project is to evaluate the safety and efficacy of a single intravitreal injection of ONL1204 Ophthalmic Solution as an adjunct to standard-of-care surgical repair in subjects with macula-off, rhegmatogenous retinal detachment.	
<u>University Employee; University Title; Relationship with ONL Therapeutics, Inc.</u>	
<ul style="list-style-type: none"> David Zacks; Research Professor, Ophthalmology and Visual Sciences; Board of Directors Member 	

Project #8

SBIR Phase II Subcontract Agreement between the University and PhotoSonoX LLC Reviewed by the Medical School Conflict of Interest Board	
<u>Project Information</u>	
Title: The development of photo-mediated ultrasound therapy for choroidal neovascularization	U-M Project ID: 23-PAF05702
Direct Sponsor: PhotoSonoX LLC	Prime Sponsor: National Institutes of Health
Principal Investigator/Department: Yannis Paulus, Ophthalmology and Visual Science	
Project Duration: Three (3) Years	Funding Support: \$917,280
Purpose: The purpose of this project is to develop photo-mediated ultrasound therapy (PUT) for safe and efficient treatment of choroidal neovascularization (CNV) in patients with wet age-related macular degeneration (AMD).	
<u>University Employee; University Title; Relationship with PhotoSonoX LLC</u>	
<ul style="list-style-type: none"> Yannis Paulus; Associate Professor, Ophthalmology and Visual Science; Partial Owner Xueding Wang; Professor, Biomedical Engineering; Partial Owner 	

Project #9

SBIR Phase II Subcontract Agreement between the University and Saros Therapeutics, Inc. Reviewed by the UMOR Conflict of Interest Review Committee	
<u>Project Information</u>	
Title: Process Development and Preclinical Advancement of a Novel Nanoparticle Formulation for Immune Activation	U-M Project ID: 23-PAF03539
Direct Sponsor: Saros Therapeutics, Inc.	Prime Sponsor: National Institutes of Health
Principal Investigator/Department: James Moon, Pharmaceutical Sciences	
Project Duration: Two (2) Years	Funding Support: \$306,019
Purpose: The purpose of this project is to generate new fundamental knowledge in the development of a novel cancer immunotherapy, and lead to new strategies for improving cancer patient outcomes.	
<u>University Employee; University Title; Relationship with Saros Therapeutics, Inc.</u>	
<ul style="list-style-type: none">James Moon; Professor, Pharmaceutical Sciences; Partial Owner	

Project #10

STTR Phase I Subcontract Agreement between the University and Tulip Make Me Move Desk, LLC Reviewed by the Medical School Conflict of Interest Board	
<u>Project Information</u>	
Title: Bohnen STTR Ph 1 A0: Development of elastic standing-enhanced dynamic standing desk (ESEDESK) in Parkinson's disease	U-M Project ID: 23-PAF06221
Direct Sponsor: Tulip Make Me Move Desk, LLC	Prime Sponsor: National Institutes of Health
Principal Investigator/Department: Nicholas Bohnen, Radiology	
Project Duration: One (1) Year	Funding Support: \$141,877
Purpose: The purpose of this project is to develop and clinically test an elastic standing-enhanced DSK (ESEDESK) prototype.	
<u>University Employee; University Title; Relationship with Tulip Make Me Move Desk, LLC</u>	
<ul style="list-style-type: none">Nicolaas Bohnen; Professor, Radiology; Partial Owner	