

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

March 2021

Attachment A

Project #1

Amendment to Research Agreement between the University and Ascentage Pharma Group Corporation, Ltd. Reviewed by the Medical School Conflict of Interest Board	
<u>Project Information</u>	
Title: CTSU_2018.127_Swiecicki_Ascentage Pharma_APG-115	U-M Project ID: 19-PAF08517
Original Direct Sponsor: Ascentage Pharma Group Corporation, Ltd. (“Ascentage”)	
Principal Investigator/Department: Paul Swiecicki, Internal Medicine-Hematology/Oncology	
Agreement Originally Approved by the Regents: September 19, 2019	
Current Project Duration: Fifty-eight (58) months Additional Time: Two (2) years	Original Funding Support: \$2,618,286 Reduction in Funding Support: -\$1,393,285
Purpose: The purpose of this amendment is to change the direct sponsor from Ascentage to the University and extend the duration so that Dr. Swiecicki may continue to perform the multicenter phase I/II trial to determine the dose-limiting toxicity (DLT) and maximally tolerated dose (MTD) for APH-115 as a monotherapy or when given in combination with carboplatin for salivary gland cancer.	
<u>University Employee; University Title; Relationship with Ascentage Pharma Group Corporation, Ltd.</u> <ul style="list-style-type: none">• Shaomeng Wang, Professor, Internal Medicine; Partial Owner	

Project #2

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 Randomized, Double-blind, Placebo-Controlled, Phase 2 Study to Evaluate the Efficacy and Safety of Mono and Combination Therapy with Monoclonal Antibodies in Participants with Mild to Moderate COVID-19 Illness (BLAZE-4); J2X-MC-PYAH	U-M Project ID: 21-PAF03791
Direct Sponsor: Eli Lilly and Company	
Principal Investigator/Department: Owen Albin, Internal Medicine-Infectious Diseases	
Project Duration: One (1) Year	Funding Support: \$144,788
Purpose: The purpose of this project is to characterize the effect of LY3819253 alone and in combination with LY3832479, compared to placebo on SARS-CoV-2 viral load. 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 February 23, 2021 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 #3

**Other Sponsored Activity between the University and EVOQ Therapeutics LLC
Reviewed by the UMOR Conflict of Interest Review Committee**

Project Information

Title: EVOQ General Service Agreement 3 through Feb 2023 **U-M Project ID:** 21-PAF04551

Direct Sponsor: EVOQ Therapeutics LLC

Principal Investigator/Department: James Moon, Pharmaceutical Sciences

Project Duration: Two (2) Years **Funding Support:** \$400,000

Purpose: The purpose of this service agreement is to produce six categories of nanodiscs and characterize them for antigen and adjuvant loading by high-performance liquid chromatography, gel permeation chromatography, and dynamic light scattering.

University Employee; University Title; Relationship with EVOQ Therapeutics LLC

- James Moon; Associate Professor, Pharmaceutical Sciences; Partial Owner
- Anna Schwendeman; Professor, Pharmacy; Partial Owner

Project #4

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

Project Information

Title: Development of vapor sensor array **U-M Project ID:** 21-PAF05570

Direct Sponsor: Healthmetryx, Inc.

Principal Investigator/Department: Xudong Fan, Biomedical Engineering

Project Duration: Six (6) Months **Funding Support:** \$323,986

Purpose: The purpose of this project is to develop an optical vapor sensor array that can detect vapor molecules in air that is inhaled into human body or in exhaled breath, as well as associated pattern recognition algorithm to extract vapor information from the sensing data.

University Employee; University Title; Relationship with Healthmetryx, Inc.

- Xudong Fan; Professor, Biomedical Engineering; Partial Owner

Project #5

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

Project Information

Title: Smartphone-based Biomechanical Analysis for Job Risk Assessment

U-M Project ID: 21-PAF00931

Direct Sponsor: Kinetica Labs, Inc.

Prime Sponsor: National Science Foundation

Principal Investigator/Department: Vineet Kamat, Civil and Environmental Engineering

Project Duration: One (1) Year

Funding Support: \$114,514

Purpose: The purpose of this project is to advance technology that will provide safety professionals with a rapid, easy, efficient, and affordable ergonomic risk assessment tool without hindering activity in real job sites through estimating forces by processing smartphone videos to address work-related musculoskeletal disorders.

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

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

Project #6

**SBIR Phase I Subcontract Agreement between the University and MONSTR Sense Technologies, LLC
Reviewed by the UMOR Conflict of Interest Review Committee**

Project Information

Title: MONSTR sense SBIR subcontract

U-M Project ID: 21-PAF05141

Direct Sponsor: MONSTR Sense Technologies, LLC

Prime Sponsor: National Science Foundation

Principal Investigator/Department: Steven Cundiff, Physics

Project Duration: Two (2) Months

Funding Support: \$5,686

Purpose: The purpose of this project at the University is to test a laser scanning microscope prototype built by MONSTR Sense Technologies, LLC.

University Employee; University Title; Relationship with MONSTR Sense Technologies, LLC

- Steven Cundiff; Professor, Physics; Partial Owner
- Eric Martin; Research Fellow, Physics; Partial Owner

Project #7

Research Agreement between the University and Sarcoma Alliance for Research through Collaboration Reviewed by the Medical School Conflict of Interest Board	
<u>Project Information</u>	
Title: Pilot Study of Circulating Tumor DNA (ctDNA) and Tumor Imaging Characteristics as Biomarkers in High-grade, Localized Leiomyosarcoma	U-M Project ID: 21-PAF03773
Direct Sponsor: Sarcoma Alliance for Research through Collaboration (“SARC”)	
Principal Investigator/Department: Scott Schuetze, Internal Medicine-Hematology/Oncology	
Project Duration: Twelve (12) Months	Funding Support: \$31,580
Purpose: The purpose of this funding is to explore whether DNA shed by high-grade leiomyosarcoma (cancer of smooth muscle) into blood can be detected by DNA sequencing techniques; whether the levels of tumor DNA in blood change during standard chemotherapy prior to surgery and after surgery; and whether such changes in tumor DNA in blood correlate with the risk of cancer relapsing (re-appearing) after surgery.	
<u>University Employee; University Title; Relationship with SARC</u>	
<ul style="list-style-type: none">Denise Reinke; Nurse Practitioner, UMH Cancer Center; President and Chief Executive Officer	

Project #8

Research Agreement between the University and Sarcoma Alliance for Research through Collaboration Reviewed by the Medical School Conflict of Interest Board	
<u>Project Information</u>	
Title: SARC043: Pilot Study of ctDNA and Imaging Characteristics as Biomarkers of Disease-related Outcomes in Patients with Localized Leiomyosarcoma Receiving Chemotherapy	U-M Project ID: 21-PAF06122
Direct Sponsor: Sarcoma Alliance for Research through Collaboration (“SARC”)	
Principal Investigator/Department: Scott Schuetze, Internal Medicine-Hematology/Oncology	
Project Duration: Three (3) Years	Funding Support: \$54,500
Purpose: The purpose of this project is to evaluate the association between tumor characteristics assessed by contrast-enhanced MRI and location with presence of ctDNA in patients with localized, high-grade leiomyosarcoma.	
<u>University Employee; University Title; Relationship with SARC</u>	
<ul style="list-style-type: none">Denise Reinke; Nurse Practitioner, UMH Cancer Center; President and Chief Executive Officer	