

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

June 2023

Attachment A

Project #1

Amendment to STTR Phase II Subcontract Agreement between the University and Courage Therapeutics, Inc. Reviewed by the UMOR Conflict of Interest Review Committee	
<u>Project Information</u>	
Title: Development of Novel Melanocortin-4 Receptor Peptide Agonists for the Treatment of MC4R Haploinsufficiency	U-M Project ID: 23-PAF07526
Direct Sponsor: Courage Therapeutics, Inc.	Prime Sponsor: National Institutes of Health
Principal Investigator/Department: Roger Cone, Life Sciences Institute	
Agreement Originally Approved by the Regents: March 24, 2022	
Project Duration: Two (2) Years	Initial Funding Support: \$391,567 Additional Funding Support: \$350,066
Purpose: The purpose of this amendment is to add funds and expand the scope of the project so that Dr. Cone may research the physiological functions of the melanocortin-3 receptor (MC3R) antagonist peptide.	
<u>University Employee; University Title; Relationship with Courage Therapeutics, Inc.</u> <ul style="list-style-type: none">• Roger Cone; Vice Provost and Director of the Biosciences Initiative, Executive Vice President for Academic Affairs, and Director of the Life Sciences Institute; Partial Owner	

Project #2

Amendment to Phase I Subcontract Agreement between the University and Loxo Oncology, Inc. (acquired by Eli Lilly and Company) Reviewed by the Medical School Conflict of Interest Board	
<u>Project Information</u>	
Title: A Phase 1 Study of Oral LOXO-260 in Patients with RET Fusion-Positive Solid Tumors, Medullary Thyroid Cancer, and Other Tumors with RET Activation Refractory to Selective RET Inhibitors	U-M Project ID: 23-PAF06287
Direct Sponsor: Medpace, Inc.	Prime Sponsor: Loxo Oncology, Inc.
Principal Investigator/Department: Francis Worden, Internal Medicine – Hematology/Oncology	
Agreement Originally Approved by the Regents: June 16, 2022	
Project Duration: Five (5) Years	Initial Funding Support: \$488,026 Additional Funding Support: \$13,420
Purpose: The purpose of this amendment is to add funds so that Dr. Worden may continue to evaluate the pharmacokinetics (PK), safety, and preliminary efficacy of LOXO-260 in RET mutant or RET rearranged NSCLC, thyroid cancer, or patients with other RET rearranged solid tumors that have previously been treated with a selective RET inhibitor.	
<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 and Dean of the Medical School; Board of Directors Member	

Project #3

Amendment to Subcontract Agreement between the University and Loxo Oncology, Inc. (acquired by Eli Lilly and Company) Reviewed by the Medical School Conflict of Interest Board	
<u>Project Information</u>	
Title: A Phase 1/2 Study of Oral Selpercatinib (LOXO-292) in Patients with Advanced Solid Tumors, Including RET Fusion-Positive Solid Tumors, Medullary Thyroid Cancer, and Other Tumors with RET Activation	U-M Project ID: 23-PAF06707
Direct Sponsor: Medpace, Inc.	Prime Sponsor: Loxo Oncology, Inc.
Principal Investigator/Department: Francis Worden, Internal Medicine – Hematology/Oncology	
Original Project Duration: Five (5) Years, One (1) Month Additional Time: Three (3) Months	Initial Funding Support: \$555,260 Additional Funding Support: \$10,702
Purpose: The purpose of this project is to determine the maximum tolerated dose (MTD)/recommended dose for further study of oral LOXO-292 in patients with advanced solid tumors, including RET-fusion non-small cell lung cancer (NSCLC), medullary thyroid cancer (MTC), and other tumors with increased RET activity.	
Original Award Information/Special Circumstances: This project began on July 10, 2018. Eli Lilly and Company acquired Loxo Oncology, Inc. after the original agreement had been signed. The agreement is being amended to add funds and time so that Dr. Worden may determine the maximum tolerated dose (MTD)/recommended Phase 2 dose (RP2D) of selpercatinib.	
<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 and Dean of the Medical School; Board of Directors Member	

Project #4

Second Amendment to Research Agreement between the University and Ningbo Inlight Technology Co., Ltd. Reviewed by the UMOR Conflict of Interest Review Committee	
<u>Project Information</u>	
Title: Correlation between visual appearance and microstructures of synthetic color elements	U-M Project ID: 23-PAF07215
Direct Sponsor: Ningbo Inlight Technology Co., Ltd.	
Principal Investigator/Department: L. Jay Guo, Electrical Engineering and Computer Science – Electrical and Computer Engineering (EECS-ECE) Division	
Original Project Duration: Thirty-Four (34) Months Additional Time: One (1) Year	Current Funding Support: \$382,743 Additional Funding Support: \$129,506
Purpose: The purpose of this amendment is to add additional funds and time so that Dr. Guo and a student may continue to develop novel approaches to the design and fabrication of synthetic or structural colors, and collaborate with Inlight engineers on applying the resulting colored pigments in coatings for potential applications.	
<u>University Employee; University Title; Relationship with Ningbo Inlight Technology Co., Ltd.</u> <ul style="list-style-type: none">• L. Jay Guo; Professor, EECS-ECE Division; Partial Owner	

Project #5

SBIR Phase II Subcontract Agreement between the University and Vortex Hydro Power LLC (dba Vortex Hydro Energy) Reviewed by the UMOR Conflict of Interest Review Committee	
<u>Project Information</u>	
Title: Integrated Current-Wave Hydrokinetic Energy Harvester for Community Resilience and Benefits to Aquatic Fauna	U-M Project ID: 23-PAF06674
Direct Sponsor: Vortex Hydro Power LLC	Prime: U.S. Department of Energy
Principal Investigator/Department: Michael Bernitsas, Naval Architecture and Marine Engineering	
Project Duration: Two (2) Years	Funding Support: \$213,764
Purpose: The purpose of this project is to improve the design of three products Vortex Hydro Power LLC is building to create VIVACE converters for use in mild currents, mild environments, and harsh environments.	
<u>University Employee; University Title; Relationship with Vortex Hydro Power LLC</u> <ul style="list-style-type: none">• Michael Bernitsas; Professor, Naval Architecture and Marine Engineering; Partial Owner	