

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 2022

Attachment A

Project #1

Amendment to STTR Phase II Subcontract Agreement between the University and ATGC, Inc. Reviewed by the Medical School Conflict of Interest Board	
<u>Project Information</u>	
Title: Novel methods to improve nuclease mediated homologous recombination - STTR Phase II	U-M Project ID: 21-PAF06344
Direct Sponsor: ATGC, Inc.	Prime Sponsor: National Institutes of Health
Principal Investigator/Department: Jifeng Zhang, Cardiology	
Agreement Initially Approved by Regents: May 20, 2021	
Project Duration: Two (2) Years	Initial Funding Support: \$780,000 Additional Funding Support: \$39,000
Purpose: The purpose of this amendment is to correct the amount of funding awarded for Dr. Zhang to perform a project to enhance the safety and efficacy of gene editing, propelling novel mi-Cas9 tools closer to an emerging multi-billion-dollar market of research and therapeutic.	
<u>University Employee; University Title; Relationship with ATGC, Inc.</u> <ul style="list-style-type: none">• Jie Xu; Research Associate Professor, Cardiology; Partial Owner• Yuqing Chen; Professor, Cardiology; Partial Owner	

Project #2

Research Agreement between the University and Courage Therapeutics, Inc. Reviewed by the UMOR Conflict of Interest Review Committee	
<u>Project Information</u>	
Title: Metreleptin Comparison for Courage Therapeutics	U-M Project ID: 22-PAF06924
Direct Sponsor: Courage Therapeutics, Inc.	
Principal Investigator/Department: Isin Cakir, Life Sciences Institute	
Project Duration: Six (6) Months	Funding Support: \$21,185
Purpose: The purpose of this project is to compare the Myalept (also called, metreleptin) from Amryt Pharma and the human leptin produced for Courage Therapeutics, Inc. at the Center for Structural Biology at the Life Sciences Institute.	
<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 #3

**Amendment to Research Agreement between the University and Courage Therapeutics, Inc.
Reviewed by the UMOR Conflict of Interest Review Committee**

Project Information

Title: Characterization of Courage MC3R agonist peptides

U-M Project ID: 22-PAF06328

Direct Sponsor: Courage Therapeutics, Inc.

Principal Investigator/Department: Roger Cone, Life Sciences Institute

Agreement Initially Approved by Regents: March 26, 2020

Project Duration: Two (2) Years
Additional Time: Five (5) Months

Funding Support: \$2,006,201
Additional Funding Support: \$69,821

Purpose: The purpose of this amendment is add additional funds and time so that the Cone Lab may evaluate peptide assets for B-arrestin engagement, plasma stability, protein binding and in vivo acute feeding to support the evaluation of a potential collaboration with Courage Therapeutics, Inc.

University Employee; University Title; Relationship with Courage Therapeutics, Inc.

- 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 #4

**Amendment to Research Agreement between the University and Lassen Peak, Inc.
Reviewed by the UMOR Conflict of Interest Review Committee**

Project Information

Title: Radar Signal Processing on FPGA

U-M Project ID: 22-PAF07023

Direct Sponsor: Lassen Peak, Inc.

Principal Investigator/Department: Ehsan Afshari, Electrical Engineering and Computer Science – Electrical and Computer Engineering (EECS-ECE) Division

Agreement Initially Approved by Regents: February 18, 2021

Project Duration: Four (4) months
Additional Time: Twenty (20) months

Funding Support: \$34,147
Additional Funding Support: \$30,000

Purpose: The purpose of this amendment is to add additional funds and time so that Dr. Afshari may now complete the task of characterization of the radar array, finding its beam pattern, transmitted power and phase noise, receiver noise figure and sensitivity, power consumption and overall noise of the system for Lassen Peak, Inc.

University Employee; University Title; Relationship with Lassen Peak, Inc.

- Ehsan Afshari; Professor, EECS - ECE; Partial Owner

Project #5

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

Project Information

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: 22-PAF05953

Direct Sponsor: Medpace, Inc.

Prime Sponsor: Loxo Oncology, Inc.

Principal Investigator/Department: Francis Worden, Internal Medicine – Hematology/Oncology

Project Duration: Five (5) Years

Funding Support: \$488,026

Purpose: The purpose of this project is 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.

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