

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

July 2022

Attachment A

Project #1

STTR Phase I Subcontract Agreement between the University and Eleven Therapeutics Corporation Reviewed by the UMOR Conflict of Interest Review Committee and Medical School Conflict of Interest Board	
<u>Project Information</u>	
Title: Development of negative allosteric modulators of the mu-opioid receptor for the management of opioid use disorder	U-M Project ID: 22-PAF00806
Direct Sponsor: Eleven Therapeutics Corporation	Prime Sponsor: National Institutes of Health
Principal Investigator/Department: John Traynor, Pharmacology	
Project Duration: One (1) Year	Initial Funding Support: \$162,000
Purpose: The purpose of this project is to demonstrate the negative allosteric modulator (NAM) compounds have activity to reverse the actions of abused opioid drugs, including fentanyl.	
<u>University Employee; University Title; Relationship with Eleven Therapeutics Corporation</u> <ul style="list-style-type: none">• Andrew Alt; Associate Research Scientist and Director of the Center for Chemical Genomics, Life Sciences Institute; Partial Owner• John Traynor; Research Professor and Associate Chair, Pharmacology; Partial Owner	

Project #2

SBIR Phase II Subcontract Agreement between the University and EVOQ Therapeutics LLC Reviewed by the UMOR Conflict of Interest Review Committee	
<u>Project Information</u>	
Title: New Approach for Immune Modulation Against T1D	U-M Project ID: 22-PAF05921
Direct Sponsor: EVOQ Therapeutics LLC	Prime Sponsor: National Institutes of Health
Principal Investigator/Department: James Moon, Pharmaceutical Sciences	
Project Duration: Two (2) Years	Initial Funding Support: \$300,000
Purpose: The purpose of this project is to develop new technologies for inducing immune tolerance against type-I diabetes (T1D).	
<u>University Employee; University Title; Relationship with EVOQ Therapeutics LLC</u> <ul style="list-style-type: none">• James Moon; Professor, Pharmaceutical Sciences; Partial Owner• Anna Schwendeman; Professor, Pharmaceutical Sciences; Partial Owner	

Project #3

**SBIR Phase I Subcontract Agreement between the University and EVOQ Therapeutics LLC
Reviewed by the UMOR Conflict of Interest Review Committee**

Project Information

Title: Novel Immunotherapy Against MOG Antibody Disease

U-M Project ID: 22-PAF06161

Direct Sponsor: EVOQ Therapeutics LLC

Prime Sponsor: National Institutes of Health

Principal Investigator/Department: James Moon, Pharmaceutical Sciences

Project Duration: Six (6) Months

Initial Funding Support: \$58,355

Purpose: The purpose of this project is to synthesize nanodiscs formulating with human myelin oligodendrocyte glycoprotein (MOG) antigens.

University Employee; University Title; Relationship with EVOQ Therapeutics LLC

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

Project #4

**Amendment to Subcontract Agreement between the University and Jacobs Engineering Group Inc.
Reviewed by the UMOR Conflict of Interest Review Committee**

Project Information

Title: Durable Anti-fog Coatings for Combat Eye Protection and Transparent Surfaces

U-M Project ID: 22-PAF07837

Direct Sponsor: Jacobs Engineering Group Inc.

Prime Sponsor: Department of Defense - Air Force

Principal Investigator/Department: Anish Tuteja, Materials Science and Engineering

Agreement Initially Approved by Regents: September 23, 2021

Project Duration: Five (5) Months

Initial Funding Support: \$250,000

Additional Time: Nine (9) Months

Additional Funding Support: \$179,000

Purpose: The purpose of this amendment is to add funds and time so that Dr. Tuteja may continue his efforts to develop durable, transparent, anti-fog coating for combat eye protection.

University Employee; University Title; Relationship with Jacobs Engineering Group Inc.

- Glenn Daigger; Professor, Civil and Environmental Engineering; Partial Owner

Project #5

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 3 Open-Label, Randomized Study of Fixed Duration Pirtobrutinib (LOXO-305) plus Venetoclax and Rituximab versus Venetoclax and Rituximab in Previously Treated Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma

U-M Project ID: 22-PAF05533

Direct Sponsor: IQVIA RDS, Inc.

Prime Sponsor: Loxo Oncology, Inc.

Principal Investigator/Department: Jing Christine Ye, Internal Medicine - Hematology/Oncology

Project Duration: Ten (10) Years

Initial Funding Support: \$1,041,344

Purpose: The purpose of this global study is to compare the efficacy and safety of fixed duration venetoclax and rituximab with or without pirtobrutinib, in chronic lymphocytic leukemia and small lymphocytic lymphoma (CLL/SLL) patients who have received at least one prior line of therapy that may include a covalent Bruton's tyrosine kinase (BTK) 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

Project #6

Second Amendment to Other Sponsored Activity Agreement between the University and Rappta Therapeutics Oy

Reviewed by the Medical School Conflict of Interest Board

Project Information

Title: Testing of small molecule PP2A activators in cellular and in vivo systems

U-M Project ID: 22-PAF07236

Direct Sponsor: Rappta Therapeutics Oy

Principal Investigator/Department: Goutham Narla, Internal Medicine - Genetic Medicine

Agreement Initially Approved by Regents: May 21, 2020

First Amendment Approved by Regents: December 9, 2021

Current Project Duration: Thirty-One (31) Months

Current Funding Support: \$2,250,000
Additional Funding Support: \$50,000

Purpose: The purpose of this amendment is to add funds so that Dr. Narla may perform additional testing on the effects of a series of small molecule activators of PP2A on a series of cancer cell lines.

University Employee; University Title; Relationship with Rappta Therapeutics Oy

- Goutham Narla; Professor, Internal Medicine - Genetic Medicine; Partial Owner

Project #7**Amendment to Other Sponsored Activity Agreement between the University and Rappta Therapeutics Oy
Reviewed by the Medical School Conflict of Interest Board****Project Information****Title:** Characterizing role of novel PP2A activators in human cancer**U-M Project ID:** 22-PAF07237**Direct Sponsor:** Rappta Therapeutics Oy**Principal Investigator/Department:** Goutham Narla, Internal Medicine - Genetic Medicine**Agreement Initially Approved by Regents:** October 21, 2021**Project Duration:** Ten (10) Months
Additional Time: Seven (7) Months**Initial Funding Support:** \$750,000
Additional Funding Support: \$650,000**Purpose:** The purpose of this amendment is to add funds and time so that Dr. Narla may do additional testing on the effects of a series of small molecule activators of PP2A on a series of cancer cell lines.**University Employee; University Title; Relationship with Rappta Therapeutics Oy**

- Goutham Narla; Professor, Internal Medicine - Genetic Medicine; Partial Owner