

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 2021

Attachment A

Project #1

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, Internal Medicine-Cardiology	
Project Duration: Two (2) Years	Funding Support: \$780,000
Purpose: The purpose of this project is to enhance the safety and efficacy of gene editing, propelling novel mi-Cas9 tools closer to viability as both research tools and therapeutics in an emerging multi-billion-dollar market.	
<u>University Employee; University Title; Relationship with ATGC Inc</u> <ul style="list-style-type: none">• Yuqing Chen; Professor, Internal Medicine-Cardiovascular Medicine; Partial Owner• Jie Xu; Research Associate Professor, Internal Medicine-Cardiovascular Medicine; Partial Owner	

Project #2

SBIR Phase I Subcontract Agreement between the University and ATGC Inc Reviewed by the Medical School Conflict of Interest Board	
<u>Project Information</u>	
Title: Knock-in Rabbits for the Manufacture of Chimeric Anti-thymocyte Globulin - SBIR Phase I	U-M Project ID: 21-PAF06357
Direct Sponsor: ATGC Inc	Prime Sponsor: National Institutes of Health
Principal Investigator/Department: Dongshan Yang, Internal Medicine-Cardiology	
Project Duration: One (1) Year	Funding Support: \$84,587
Purpose: The purpose of this project is to establish the feasibility of genetically engineering the rabbit immune system for the production of chimeric rabbit anti-thymocyte globulin (rATG) with human constant regions.	
<u>University Employee; University Title; Relationship with ATGC Inc</u> <ul style="list-style-type: none">• Yuqing Chen; Professor, Internal Medicine-Cardiovascular Medicine; Partial Owner• Jie Xu; Research Associate Professor, Internal Medicine-Cardiovascular Medicine; Partial Owner	

Project #3

**Other Sponsored Activity between the University and Entos, Inc.
Reviewed by the UMOR Conflict of Interest Review Committee**

Project Information

Title: Entos Lab Manager and HTE Development

U-M Project ID: 21-PAF05612

Direct Sponsor: Entos, Inc.

Principal Investigator/Department: Timothy Cernak, Pharmacy Medicinal Chemistry

Project Duration: Two (2) Years

Funding Support: \$509,576

Purpose: The purpose of this service agreement is to explore automated chemistry workflows and execute the synthesis of chemical libraries.

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

- Timothy Cernak; Assistant Professor, Medicinal Chemistry; Partial Owner

Project #4

**SBIR Phase II Subcontract Agreement between the University and FibrosIX Inc.
Reviewed by the UMOR Conflict of Interest Review Committee**

Project Information

Title: Pre-clinical efficacy and safety of a pirin inhibitor for mitigating bleomycin- and radiation-induced lung fibrosis

U-M Project ID: 21-PAF06533

Direct Sponsor: FibrosIX Inc.

Prime Sponsor: National Institutes of Health

Principal Investigator/Department: Dipankar Ray, Radiation Oncology

Project Duration: Two (2) Years

Funding Support: \$418,403

Purpose: The purpose of this project is to test the efficacy of a novel anti-fibrotic therapeutic, developed by FibrosIX Inc., in a preclinical model of radiation-induced lung fibrosis.

University Employee; University Title; Relationship with FibrosIX Inc.

- Scott Larsen; Research Professor, Medicinal Chemistry; Partial Owner

Project #5

**STTR Phase I Subcontract between the University and GeneToBe, LLC
Reviewed by the Medical School Conflict of Interest Board**

Project Information

Title: Gene-editing therapy to treat vision loss in Usher Syndrome type 3 - STTR Phase I

U-M Project ID: 21-PAF06358

Direct Sponsor: GeneToBe, LLC

Prime Sponsor: National Institutes of Health-
National Eye Institute

Principal Investigator/Department: Dongshan Yang, Internal Medicine-Cardiology

Project Duration: One (1) Year

Funding Support: \$90,000

Purpose: The purpose of this project is to test the feasibility and safety of miCas9 mediated gene editing therapy for USH3A using cultured rabbit fibroblasts and retina explants isolated from the USH3A KI rabbit model U-M has established.

University Employee; University Title; Relationship with GeneToBe, LLC

- Yuqing Chen; Professor, Internal Medicine-Cardiovascular Medicine; Partial Owner

Project #6

**Research Agreement between the University and ONL Therapeutics, Inc.
Reviewed by the Medical School Conflict of Interest Board**

Project Information

Title: Feasibility of Fas inhibition in preventing photoreceptor cell death in inherited retinal degeneration

U-M Project ID: 21-PAF05252

Direct Sponsor: ONL Therapeutics, Inc.

Principal Investigator/Department: David Zacks, Ophthalmology & Visual Science

Project Duration: Two (2) Years

Funding Support: \$495,072

Purpose: The purpose of this project is to engage the laboratory of Dr. Zacks to further test the potential for two of the company's Fas inhibitors to protect photoreceptor cells, the results of which may lead to eventual therapeutic benefit concerning inherited retinal degeneration.

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

- David Zacks; Professor, Ophthalmology and Visual Sciences; Partial Owner

Project #7

**Subcontract Agreement between the University and Sublime, LLC
Reviewed by the UMOR Conflict of Interest Review Committee**

Project Information

Title: Study of Global Health APIs for Suitability to Novel Technology **U-M Project ID:** 21-PAF06543

Direct Sponsor: Sublime, LLC

Prime Sponsor: Bill and Melinda Gates Foundation

Principal Investigator/Department: Max Shtein, Materials Science and Engineering

Project Duration: Two (2) Years

Funding Support: \$500,642

Purpose: The purpose of this project is to have U-M researchers in Dr. Shtein's lab use printing technology invented in Dr. Shtein's lab to evaluate potential antiviral treatment candidates for COVID and other viruses impacting the developing world.

University Employee; University Title; Relationship with Sublime, LLC

- Max Shtein; Professor, Materials Science and Engineering; Partial Owner

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 April 25, 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.