

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

September 2023

Attachment A

Project #1

SBIR Phase I Subcontract Agreement between the University and Arbor Batteries LLC Reviewed by the UMOR Conflict of Interest Review Committee	
<u>Project Information</u>	
Title: Li-ion Batteries with 3-D Structured Anodes to Minimize Inactive Materials and Improve Safety	U-M Project ID: 23-PAF04851
Direct Sponsor: Arbor Batteries LLC	Prime: U.S. Department of Energy
Principal Investigator/Department: Neil Dasgupta, Mechanical Engineering	
Project Duration: One (1) Year	Funding Support: \$60,000
Purpose: The purpose of this project develop and optimize a laser ablation process to 3-D pattern high-loading Li-ion battery anodes.	
<u>University Employee; University Title; Relationship with Arbor Batteries LLC</u>	
<ul style="list-style-type: none">• Neil Dasgupta; Associate Professor, Mechanical Engineering; Partial Owner• Jeff Sakamoto; Professor, Mechanical Engineering; Partial Owner	

Project #2

STTR Phase I Subcontract Agreement between the University and ATGC, Inc. Reviewed by the Medical School Conflict of Interest Board	
<u>Project Information</u>	
Title: Development of High-Affinity Rabbit Monoclonal Antibodies Against CitH3 for Sepsis Diagnosis and Prognosis	U-M Project ID: 24-PAF00671
Direct Sponsor: ATGC, Inc.	Prime: National Institutes of Health
Principal Investigator/Department: Yongqing Li, MM GSA Administration-Colorectal Surgery	
Project Duration: One (1) Year	Funding Support: \$195,000
Purpose: The purpose of this project is to develop citrullinates histone H3 (CitH3)-based diagnostic and prognostic tools for sepsis. They propose to develop high-affinity (at pM range) rabbit-mAbs against CitH3 (Phase 1), with the ultimate goal to develop CitH3 centered diagnosis and prognosis panels for sepsis-ALI (future Phase II and beyond).	
<u>University Employee; University Title; Relationship with ATGC, Inc.</u>	
<ul style="list-style-type: none">• Yuqing Chen; Professor, Cardiovascular Medicine; Partial Owner• Jie Xu; Research Associate Professor, Internal Medicine - Cardiology; Partial Owner	

Project #3

STTR Phase I Subcontract Agreement between the University and Cerillo, Inc. Reviewed by the UMOR Conflict of Interest Review Committee	
<u>Project Information</u>	
Title: STTR Phase I: Accelerating scientific discovery with BenchtopAI	U-M Project ID: 23-PAF03712
Direct Sponsor: Cerillo, Inc.	Prime: National Science Foundation
Principal Investigator/Department: Paul Jensen, Biomedical Engineering	
Project Duration: Seven (7) Months	Funding Support: \$98,819
Purpose: The purpose of this project is to develop BenchtopAI, an AI system that augments human scientists.	
<u>University Employee; University Title; Relationship with Cerillo, Inc.</u>	
<ul style="list-style-type: none">• Paul Jensen; Assistant Professor, Biomedical Engineering; Partial Owner	

Project #4

Research Agreement between the University and Eli Lilly and Company Reviewed by the Medical School Conflict of Interest Board	
<u>Project Information</u>	
Title: Once Weekly Tirzepatide Compared to Metformin in Obese Participants with PCOS: A Randomized, Open-label, Active-Comparator Trial (IIRT)	U-M Project ID: 23-PAF05933
Direct Sponsor: Eli Lilly and Company	
Principal Investigator/Department: David Broome, Metabolism, Endocrinology, & Diabetes	
Project Duration: Three (3) Years	Funding Support: \$671,547
Purpose: The purpose of this project is to investigate and compare the effectiveness and safety of once weekly subcutaneous tirzepatide in obese patients with polycystic ovary syndrome (PCOS).	
<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 #5

Research Agreement between the University and Eli Lilly and Company Reviewed by the Medical School Conflict of Interest Board	
<u>Project Information</u>	
Title: UNC13A modulation in models of ALS/FTD	U-M Project ID: 23-PAF06726
Direct Sponsor: Eli Lilly and Company	
Principal Investigator/Department: Sami Barmada, Neurology	
Project Duration: Two (2) Years	Funding Support: \$265,000
Purpose: The purpose of this project is to develop therapeutic strategies aimed at maintaining the expression of UNC13A (unc-13 homologue A) and other TDP43 (transactive response DNA binding protein of 43) targets in models (amyotrophic lateral sclerosis) ALS and (frontotemporal dementia) FTD, thereby preventing downstream impacts on neuronal function and survival.	
<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 #6

Research Agreement between the University and Eli Lilly and Company Reviewed by the Medical School Conflict of Interest Board	
<u>Project Information</u>	
Title: Impact of Weekly Dual Glucose-dependent Insulinotropic Polypeptide/Glucagon-like Peptide-1 Receptor Agonist on Reducing Prandial Insulin Use in Type 2 Diabetes Inadequately Controlled on Multiple Daily Injections of Insulin: A Randomized Controlled Trial	U-M Project ID: 24-PAF00138
Direct Sponsor: Eli Lilly and Company	
Principal Investigator/Department: Richard Auchus, Metabolism, Endocrinology, & Diabetes	
Project Duration: Three (3) Years	Funding Support: \$5,064,066
Purpose: The purpose of this project is to investigate the percent reduction and/or substitution of prandial insulin associated with tirzepatide use in patients with inadequately controlled type 2 diabetes on basal plus prandial insulin therapy.	
<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 #7

STTR Phase I Subcontract Agreement between the University and GeneToBe Inc. Reviewed by the Medical School Conflict of Interest Board	
<u>Project Information</u>	
Title: Developing novel Type 1 CRISPR tools for gene editing therapy STTR Phase I (Resubmission)	U-M Project ID: 24-PAF00866
Direct Sponsor: GeneToBe Inc.	Prime: National Institutes of Health
Principal Investigator/Department: Zhonggang Hou, Biological Chemistry	
Project Duration: One (1) Year	Funding Support: \$120,000
Purpose: The purpose of this project is to evaluate the efficacy and safety of T1 CRISPR gene therapy strategies in preclinical cell and animal models.	
<u>University Employee; University Title; Relationship with GeneToBe Inc.</u>	
<ul style="list-style-type: none"> ● Yuqing Chen; Professor, Cardiovascular Medicine; Partial Owner ● Jie Xu, Research Associate Professor, Internal Medicine-Cardiology; Partial Owner 	

Project #8

Amendment to Research Agreement between the University and iReprogram, Inc. Reviewed by the Medical School Conflict of Interest Board	
<u>Project Information</u>	
Title: iReprogram's Partnership with the University of Michigan (Rajapakse Lab) - Supplement 1	U-M Project ID: 23-PAF08546
Direct Sponsor: iReprogram, Inc.	
Principal Investigator/Department: Indika Rajapakse, Computational Medicine and Bioinformatics	
Agreement Initially Approved by the Regents: October 20, 2022	
Original Project Duration: Six (6) Months Additional Time: Thirteen (13) Months	Initial Funding Support: \$156,470 Additional Funding Support: \$157,042
Purpose: The purpose of this amendment is to add funds and time so that Dr. Rajapakse may refine a Data-guided Control (DGC) algorithm with new data from primary hepatocytes and primary hematopoietic stem cells and perform select experiments to collect data on induced Hepatocytes (iHEP) and induced Hematopoietic Stem Cells (iHSC).	
<u>University Employee; University Title; Relationship with iReprogram, Inc.</u>	
<ul style="list-style-type: none"> ● Lindsey Muir; Research Assistant Professor, Computational Medicine and Bioinformatics; Partial Owner ● Indika Rajapakse; Associate Professor, Computational Medicine and Bioinformatics; Partial Owner ● Gil Omenn; Professor, Computational Medicine and Bioinformatics; Board of Directors Member 	

Project #9

Other Sponsored Activity Agreement between the University and MDI Therapeutics, Inc. Reviewed by the Medical School Conflict of Interest Board	
<u>Project Information</u>	
Title: MDI MedChem studies	U-M Project ID: 24-PAF00234
Direct Sponsor: MDI Therapeutics, Inc.	
Principal Investigator/Department: Daniel Lawrence, Internal Medicine - Cardiology	
Project Duration: One (1) Year	Funding Support: \$55,000
Purpose: The purpose of this activity is to analyze novel compounds for plasminogen activator inhibitor-1 (PAI-1) inhibitory activity in buffer and in plasma in vitro, using a biochemical fluorometric assay.	
<u>University Employee; University Title; Relationship with MDI Therapeutics, Inc.</u>	
<ul style="list-style-type: none">● Daniel Lawrence; Professor, Internal Medicine-Cardiology; Partial Owner● Enming Su; Associate Research Scientist, Internal Medicine-Cardiology; Partial Owner	

Project #10

SBIR Phase II Subcontract Agreement between the University and PhotoSonoX LLC Reviewed by the Medical School Conflict of Interest Board	
<u>Project Information</u>	
Title: The development of photo-mediated ultrasound therapy for choroidal neovascularization	U-M Project ID: 24-PAF01021
Direct Sponsor: PhotoSonoX LLC	Prime: National Institutes of Health
Principal Investigator/Department: Yannis Paulus, Ophthalmology & Visual Science	
Project Duration: Three (3) Years	Funding Support: \$923,126
Purpose: The purpose of this project is to develop photo-mediated ultrasound therapy for safe and efficient treatment of choroidal neovascularization (CNV) in patients with wet age-related macular degeneration (AMD), which is the leading cause of irreversible blindness in the developed world.	
<u>University Employee; University Title; Relationship with PhotoSonoX LLC</u>	
<ul style="list-style-type: none">● Yannis Paulus; Associate Professor, Ophthalmology & Visual Science; Partial Owner● Xueding Wang; Professor, Biomedical Engineering; Partial Owner	

Project #11

Subcontract Agreement between the University and Sling Therapeutics, Inc. Reviewed by the Medical School Conflict of Interest Board	
<u>Project Information</u>	
Title: A Multicenter, Extension Study to Evaluate the Efficacy, Safety, Pharmacokinetics, and Pharmacodynamics of Two Doses of Linsitinib in Subjects with Active, Moderate to Severe Thyroid Eye Disease (TED)	U-M Project ID: 23-PAF07691
Direct Sponsor: Syneos Health, LLC	Prime: Sling Therapeutics, Inc.
Principal Investigator/Department: Christine Nelson, Ophthalmology & Visual Science	
Project Duration: Three (3) Years	Funding Support: \$135,103
Purpose: The purpose of this project is to continue to assess the efficacy, safety, pharmacokinetics, and pharmacodynamics of linsitinib in subjects who were enrolled in the prior VGN-TED-301 through Week 24.	
<u>University Employee; University Title; Relationship with Sling Therapeutics, Inc.</u>	
<ul style="list-style-type: none">● Gary Hammer; Professor, Internal Medicine – Metabolism, Endocrinology & Diabetes; Partial Owner	

Project #12

Research Agreement between the University and Tuebor Energy, Inc. Reviewed by the UMOR Conflict of Interest Review Committee	
<u>Project Information</u>	
Title: Optimization and of Aramid Nanofiber Separators for Batteries	U-M Project ID: 23-PAF07006
Direct Sponsor: Tuebor Energy, Inc.	
Principal Investigator/Department: Nicholas Kotov, Chemical Engineering	
Project Duration: Five (5) Months	Funding Support: \$205,905
Purpose: The purpose of this project is to develop aramid nanofiber (ANF) materials for ion-selective membranes for batteries and the development scalable manufacturing process for ANF-based separators.	
<u>University Employee; University Title; Relationship with Tuebor Energy, Inc.</u>	
<ul style="list-style-type: none">● Nicholas Kotov; Professor, Chemical Engineering; Partial Owner● Ahmet Emre; Research Fellow, Chemical Engineering; Partial Owner	

Project #13

Research Agreement between the University and Zakuro, Inc. Reviewed by the UMOR Conflict of Interest Review Committee	
<u>Project Information</u>	
Title: Characterization of microstructures of thin film battery materials by FIB slice & view tomography.	U-M Project ID: 24-PAF00427
Direct Sponsor: Zakuro, Inc.	
Principal Investigator/Department: Kai Sun, Materials Science and Engineering	
Project Duration: Six (6) Months	Funding Support: \$24,000
Purpose: The purpose of this project is to evaluate the uniformity of hidden interfaces between solid electrolytes and lithium in their next-generation battery materials.	
<u>University Employee; University Title; Relationship with Zakuro, Inc.</u>	
<ul style="list-style-type: none">• Jeff Sakamoto; Professor, Mechanical Engineering; Partial Owner	