

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 cursive script, appearing to read 'Rebecca Cunningham'.

Rebecca Cunningham
Vice President for Research and Innovation

February 2024

Attachment A

Project #1

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| Subcontract Agreement between the University and AmpedRNA Biosciences LLC Reviewed by the UMOR Conflict of Interest Review Committee | |
| <u>Project Information</u> | |
| Title: Develop a Rapidly-Manufacturable Mini-circRNA Vaccine that Targets Personalized Tumor Neoantigens to Eradicate Cancer | U-M Project ID: 24-PAF00075 |
| Direct Sponsor: AmpedRNA Biosciences LLC | Prime: Cancer Prevention and Research Institute of Texas |
| Principal Investigator/Department: Guizhi Zhu, Pharmaceutical Sciences | |
| Project Duration: Two (2) Years | Funding Support: \$611,226 |
| Purpose: The purpose of this project is to prepare and optimize high throughput cell-based screens for internal ribosome entry site (IRES) and KOZAK sequences and conduct in vivo immunogenicity and biodistribution studies. | |
| <u>University Employee; University Title; Relationship with AmpedRNA Biosciences LLC</u> | |
| <ul style="list-style-type: none">• Guizhi Zhu; Professor, Pharmaceutical Sciences; Partial Owner | |

Project #2

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| Other Sponsored Activity Agreement between the University and ASKO Pharma, LLC Reviewed by the UMOR Conflict of Interest Review Committee | |
| <u>Project Information</u> | |
| Title: ASKO Pharma General Service Agreement | U-M Project ID: 24-PAF03640 |
| Direct Sponsor: ASKO Pharma, LLC | |
| Principal Investigator/Department: Anna Schwendeman, Pharmaceutical Sciences | |
| Project Duration: Two (2) Years | Funding Support: \$200,000 |
| Purpose: The purpose of this activity is to have four categories of services (analytical characterization, in vivo sample analysis, large scale in vitro sample analysis, and formulation of drug products) performed in the laboratories of Dr. Anna Schwendeman and Dr. Steven Schwendeman. | |
| <u>University Employee; University Title; Relationship with ASKO Pharma, LLC</u> | |
| <ul style="list-style-type: none">• Anna Schwendeman; Professor, Pharmaceutical Sciences; Partial Owner• Steven Schwendeman; Professor, Pharmaceutical Sciences; Partial Owner• Vishalakshi Krishnan; Associate Director, Center for Research on Complex Generics; Partial Owner | |

Project #3

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| SBIR Phase II Subcontract Agreement between the University and Blue Arbor Technologies, Inc. Reviewed by the Medical School Conflict of Interest Board | |
| <u>Project Information</u> | |
| Title: Clinical Testing of an Advanced Neuroprosthetic Control System | U-M Project ID: 24-PAF03779 |
| Direct Sponsor: Blue Arbor Technologies, Inc. | Prime Sponsor: National Institutes of Health |
| Principal Investigator/Department: Deanna Gates, Kinesiology | |
| Project Duration: Two (2) Years | Funding Support: \$994,549 |
| Purpose: The purpose of this project is to test an implant for improving prosthetic control in the home environment. | |
| <u>University Employee; University Title; Relationship with Blue Arbor Technologies, Inc.</u> | |
| <ul style="list-style-type: none">● Alex Vaskov; Research Fellow, Plastic Surgery; Partial Owner● Paul Cederna; Professor, Plastic Surgery; Partial Owner● Theodore Kung; Associate Professor, Plastic Surgery; Partial Owner | |

Project #4

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| Third Amendment to Research Agreement between the University and ChromX Health Co., Ltd. Reviewed by the UMOR Conflict of Interest Review Committee | |
| <u>Project Information</u> | |
| Title: Portable GC with argon discharge photoionization detector for breath analysis - additional funds 3 | U-M Project ID: 24-PAF03578 |
| Direct Sponsor: ChromX Health Co., Ltd. | |
| Principal Investigator/Department: Xudong Fan, Biomedical Engineering | |
| Agreement Originally Approved by the Regents: July 15, 2021 First Amendment Approved by the Regents: December 8, 2022 Second Amendment Approved by the Regents: October 19, 2023 | |
| Project Duration: Three (3) Years, Two (2) Months | Current Funding Support: \$378,555 Additional Funding Support: \$108,900 |
| Purpose: The purpose of this amendment is to add additional funds so Dr. Fan may continue to develop portable GC devices with an argon discharge photoionization detector (PID) for breath analysis and conduct corresponding data analysis. | |
| <u>University Employee; University Title; Relationship with ChromX Health Co., Ltd.</u> | |
| <ul style="list-style-type: none">● Xudong Fan; Professor, Biomedical Engineering; Partial Owner | |

Project #5

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| STTR Phase I/II Subcontract Agreement between the University and GeneToBe Inc. Reviewed by the Medical School Conflict of Interest Board | |
| <u>Project Information</u> | |
| Title: Novel selective SGLT-1 inhibitors for adjunctive therapy for cystic fibrosis associated metabolic diseases - STTR | U-M Project ID: 24-PAF03696 |
| Direct Sponsor: GeneToBe Inc. | Prime Sponsor: National Institutes of Health |
| Principal Investigator/Department: Jie Xu, Internal Medicine-Cardiology | |
| Project Duration: Three (3) Years | Funding Support: \$1,150,000 |
| Purpose: The purpose of this project is to develop novel selective Sodium/glucose cotransporter 1 (SGLT-1) inhibitors as an adjunctive therapy for cystic fibrosis (CF) and to conduct preclinical testing in CF rabbits, based on Dr. Jie Xu's discovery that inhibiting SGLT-1 may benefit CF associated metabolic disorders and his prior successes in drug discovery. | |
| <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 #6

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| SBIR Phase I Subcontract Agreement between the University and ImBio Inc. Reviewed by the Medical School Conflict of Interest Board | |
| <u>Project Information</u> | |
| Title: SBIR Phase I (IMBIO) A1: LUCIFAI: Automated Detection and Quantification of LUng Cancer screening Incidental Findings using Artificial Intelligence | U-M Project ID: 24-PAF03885 |
| Direct Sponsor: ImBio Inc. | Prime: National Institutes of Health |
| Principal Investigator/Department: Ella Kazerooni, Radiology | |
| Project Duration: Six (6) Months | Funding Support: \$38,246 |
| Purpose: The purpose of this project is to build a ground truth database for development and validation of a software for automated detection and quantification of incidental findings on CT (computed tomography). | |
| <u>University Employee; University Title; Relationship with ImBio Inc.</u> | |
| <ul style="list-style-type: none">● Alnawaz Rehemtulla; Professor, Radiation Oncology; Partial Owner● Brian Ross; Research Professor, Radiology; Partial Owner | |

Project #7

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| SBIR Phase I Subcontract Agreement between the University and Innovative Biotherapies, Inc. Reviewed by the Medical School Conflict of Interest Board | |
| <u>Project Information</u> | |
| Title: Mitigation Of Traumatic Brain Injury Using Cell Directed Immunomodulatory Therapy | U-M Project ID: 24-PAF03838 |
| Direct Sponsor: Innovative Biotherapies, Inc. | Prime: National Institutes of Health |
| Principal Investigator/Department: H David Humes, Nephrology | |
| Project Duration: One (1) Year | Funding Support: \$109,617 |
| Purpose: The purpose of this project is to test a selective cytopheretic device (SCD) in a clinically relevant large animal (swine) model of traumatic brain injury to determine efficacy of SCD therapy in mitigation of inflammation and amelioration of secondary brain injury. | |
| <u>University Employee; University Title; Relationship with Innovative Biotherapies, Inc.</u> | |
| <ul style="list-style-type: none">• H. David Humes; Professor, Internal Medicine-Nephrology; Partial Owner | |

Project #8

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| 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-PAF04324 |
| Direct Sponsor: PhotoSonoX LLC | Prime: National Institutes of Health |
| Principal Investigator/Department: Yannis Paulus, Ophthalmology & Visual Science | |
| Project Duration: Three (3) Years | Funding Support: \$1,097,860 |
| Purpose: The purpose of this project is to carry out experiments on phantoms, rabbit model, and human subjects, analyze the experimental results, and report the research findings to PhotoSonoX LLC with a long-term goal of commercializing a new, non-invasive therapeutic technique for safe and efficient treatment of choroidal neovascularization (CNV) in patients with wet age-related macular degeneration (AMD). | |
| <u>University Employee; University Title; Relationship with PhotoSonoX LLC</u> | |
| <ul style="list-style-type: none">• Yannis Paulus; Professor, Ophthalmology & Visual Science; Partial Owner• Xueding Wang; Professor, Biomedical Engineering; Partial Owner | |

Project #9

Third 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:** 24-PAF03912**Direct Sponsor:** Rappta Therapeutics Oy**Principal Investigator/Department:** Goutham Narla, Internal Medicine - Genetic Medicine**Agreement Originally Approved by the Regents:** October 21, 2021**First Amendment Approved by the Regents:** July 21, 2022**Second Amendment Approved by the Regents:** March 23, 2023**Current Project Duration:** Two (2) Years, Ten (10) Months**Additional Project Duration:** One (1) Year, Six (6) Months**Current Funding Support:** \$2,400,000**Additional Funding Support:** \$1,000,000

Purpose: The purpose of this amendment is to add additional time and funds so that Dr. Narla may continue to test 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 #10

**Fifth 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: 24-PAF03913
under AWD016016

Direct Sponsor: Rappta Therapeutics Oy

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

Agreement Originally Approved by the Regents: May 21, 2020

First Amendment Approved by the Regents: December 9, 2021

Second Amendment (not funded) Approved by the Regents: July 21, 2022

Third (not funded) and Fourth Amendments Approved by the Regents: March 23, 2023

Current Project Duration: Forty-Six (46) Months

Additional Project Duration: One (1) Year, Six (6) Months

Current Funding Support: \$3,100,000

Additional Funding Support: \$750,000

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

University Employee; University Title; Relationship with Rappta Therapeutics Oy

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

Project #11

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| Amendment to SBIR Phase II Subcontract Agreement between the University and Theia Scientific, LLC Reviewed by the UMOR Conflict of Interest Review Committee | |
| <u>Project Information</u> | |
| Title: An Open Analysis Platform with In-Situ Machine Vision for Electron Microscopy - Phase IIB | U-M Project ID: 24-PAF03335 |
| Direct Sponsor: Theia Scientific, LLC | Prime: Department of Energy |
| Principal Investigator/Department: Kevin Field, Nuclear Engineering & Radiological Sciences | |
| Agreement Originally Approved by the Regents: February 17, 2022 | |
| Current Project Duration: Two (2) Years Additional Time: Two (2) Years | Current Funding Support: \$330,000 Additional Funding Support: \$330,000 |
| Purpose: The purpose of this amendment is to add funds and time so Dr. Field may extend commercialization efforts of Theia Scientific, LLCs technology and provide additional services and deliverables related to the expansion of the number of machine learning models hosted on learning platforms. | |
| <u>University Employee; University Title; Relationship with Theia Scientific, LLC</u> | |
| <ul style="list-style-type: none">• Kevin Field; Associate Professor, Nuclear Engineering & Radiological Sciences; Partial Owner | |

Project #12

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| Subcontract Agreement between the University and U.S. Good Business Lab Foundation Reviewed by the UMOR Conflict of Interest Review Committee | |
| <u>Project Information</u> | |
| Title: US Good Business Lab Foundation (BMGF) sub-grant | U-M Project ID: 24-PAF03779 |
| Direct Sponsor: U.S. Good Business Lab Foundation | Prime Sponsor: Bill and Melinda Gates Foundation |
| Principal Investigator/Department: Anant Nyshadham, Ross School of Business | |
| Project Duration: Two (2) Years, Five (5) Months | Funding Support: \$173,320 |
| Purpose: The purpose of this project is to provide course buyouts so Dr. Anant Nyshadham may oversee research operations and study female labor force participation in South Asia. | |
| <u>University Employee; University Title; Relationship with U.S. Good Business Lab Foundation</u> | |
| <ul style="list-style-type: none">• Anant Nyshadham; Associate Professor, Business Economics; Partial Owner | |