

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 2022

Attachment A

Project #1

| Amendment to SBIR Phase I Subcontract Agreement between the University and Arborsense, Inc. Reviewed by the Medical School Conflict of Interest Board and UMOR Conflict of Interest Review Committee | |
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| <u>Project Information</u> | |
| Title: Rapid and non-invasive device for drug detection through sweat - additional funds | U-M Project ID: 23-PAF01283 |
| Direct Sponsor: Arborsense, Inc. | Prime Sponsor: National Institutes of Health |
| Principal Investigator/Department: Xudong Fan, Biomedical Engineering | |
| Agreement Originally Approved by the Regents: June 25, 2020 | |
| Project Duration: Six (6) Months Additional Time: One (1) Year, Four (4) Months | Initial Funding Support: \$78,000 Additional Funding Support: \$10,357 |
| Purpose: The purpose of this amendment is to add time and funds to cover overdraft costs. | |
| <u>University Employee; University Title; Relationship with Arborsense, Inc.</u> <ul style="list-style-type: none">• Xudong Fan; Professor, Biomedical Engineering; Partial Owner• Zhaohui Zhong; Associate Professor, Electrical Engineering and Computer Science – Electrical and Computer Engineering (EECS – ECE) Division; Partial Owner• Mark Ilgen; Professor, Psychiatry; Partial Owner | |

Project #2

| STTR Phase I Subcontract Agreement between the University and ATGC, Inc. Reviewed by the Medical School Conflict of Interest Board | |
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| <u>Project Information</u> | |
| Title: Structure-based computational engineering of saCas9 PAM requirement - STTR Phase I Resub | U-M Project ID: 23-PAF00965 |
| Direct Sponsor: ATGC, Inc. | Prime Sponsor: National Institutes of Health |
| Principal Investigator/Department: Xiaoqiang Huang, Internal Medicine - Cardiology | |
| Project Duration: One (1) Year | Funding Support: \$109,000 |
| Purpose: The purpose of this project is to design staphylococcus aureus (saCas9) variants to broaden its applicability and to improve its efficacy and safety performances. | |
| <u>University Employee; University Title; Relationship with ATGC, Inc.</u> <ul style="list-style-type: none">• Jie Xu; Professor, Internal Medicine - Cardiology; Partial Owner• Yuqing Chen; Professor, Internal Medicine - Cardiology; 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

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| Title: Novel Immunotherapy Against MOG Antibody Disease | U-M Project ID: 22-PAF03420 |
| Direct Sponsor: EVOQ Therapeutics LLC | Prime Sponsor: National Institutes of Health |
| Principal Investigator/Department: James Moon, Pharmaceutical Sciences | |
| Project Duration: Six (6) Months | Funding Support: \$58,129 |

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 STTR Phase I Subcontract Agreement between the University and Mekanistic Therapeutics, Inc. (formerly Mekanistic Therapeutics LLC)
Reviewed by the Medical School Conflict of Interest Board**

Project Information

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| Title: Supplement: Development of Novel Therapeutic Molecules for Treatment of Squamous Head and Neck Cancers | U-M Project ID: 23-PAF01228 |
| Direct Sponsor: Mekanistic Therapeutics, Inc. | Prime Sponsor: National Institutes of Health |

Principal Investigator/Department: Judith Leopold, Radiology

Agreement Originally Approved by the Regents: February 18, 2021

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| Project Duration: One (1) Year Additional Time: Six (6) Months | Initial Funding Support: \$119,050 Additional Funding Support: \$31,508 |
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Purpose: The purpose of this amendment is to add funds and time in support of Dr. Leopold's continued efforts to provide preclinical proof of concept in the monotherapy development of a lead EGFR/PI3K inhibitor that is ideally suited to treat squamous head and neck cancers.

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

- Judith Leopold; Research Professor, Radiology; Partial Owner
- Christopher Whitehead; Chemist Staff Specialist, Radiology; Partial Owner
- Mary Stewart; Contract and Grant Specialist, Radiology; Partial Owner

Project #5

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| Research Agreement between the University and NS Nanotech Inc. Reviewed by the UMOR Conflict of Interest Review Committee | |
| <u>Project Information</u> | |
| Title: Core-Shell Photonic Crystal LED Structures for Enhanced Efficiency | U-M Project ID: 23-PAF00760 |
| Direct Sponsor: NS Nanotech Inc. | |
| Principal Investigator/Department: Zetian Mi, EECS-ECE Division | |
| Project Duration: One (1) Year | Funding Support: \$950,000 |
| Purpose: The purpose of this project is to further develop InGaN nanowire technology and to demonstrate microscale InGaN nanowire LED structures with enhanced efficiency and functionality. | |
| <u>University Employee; University Title; Relationship with NS Nanotech Inc.</u> | |
| <ul style="list-style-type: none">• Zetian Mi; Professor, EECS-ECE Division; Partial Owner | |

Project #6

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| Other Sponsored Activity Agreement between the University and OGB1, Inc. (doing business as Asalyxa Bio) Reviewed by the UMOR Conflict of Interest Review Committee | |
| <u>Project Information</u> | |
| Title: ASX100 lot comparison using mouse model of acute lung injury | U-M Project ID: 22-PAF08161 |
| Direct Sponsor: Asalyxa Bio | |
| Principal Investigator/Department: Lola Eniola-Adefeso, Chemical Engineering | |
| Project Duration: Three (3) Months | Funding Support: \$19,816 |
| Purpose: The purpose of this activity is to compare several iterations of Asalyxa Bio's manufactured PolyA particles to those that are manufactured by Dr. Eniola-Adefeso's U-M lab, using a mouse model of acute lung injury. | |
| <u>University Employee; University Title; Relationship with OGB1, Inc. (doing business as Asalyxa Bio)</u> | |
| <ul style="list-style-type: none">• Lola Eniola-Adefeso; Professor, Chemical Engineering; Partial Owner• Bruce Auerbach; Mentor-in-Residence, OVPR Innovation Partnerships; Partial Owner | |

Project #7

Subcontract Agreement between the University and Sling Therapeutics, Inc. (formerly Vasaragen, Inc.) Reviewed by the Medical School Conflict of Interest Board

Project Information

Title: A Phase 2b, Randomized, Double-Mask, Placebo-Controlled, Study to Evaluate the Safety, Pharmacokinetics and Efficacy of Linsitinib in Subjects with Active, Moderate to Severe Thyroid Eye Disease (TED)

U-M Project ID: 22-PAF05171

Direct Sponsor: Syneos Health, LLC

Prime Sponsor: Sling Therapeutics, Inc.

Principal Investigator/Department: Christine Nelson, Ophthalmology & Visual Science

Project Duration: Four (4) Years

Funding Support: \$193,791

Purpose: The purpose of this project is to study the effect of linsitinib versus placebo on the proptosis responder rate at Week 24. Responder rate is the percentage of subjects with a ≥ 2 mm reduction from Baseline in the primary study eye without deterioration (≥ 2 mm increase) of proptosis in the contralateral non-study eye.

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

- Gary Hammer; Professor, Internal Medicine – Metabolism, Endocrinology & Diabetes; Partial Owner

Project #8

SBIR Phase I Subcontract Agreement between the University and Therapeutics System Research Lab, Inc. (TSRL, Inc.) Reviewed by the Medical School Conflict of Interest Board

Project Information

Title: Novel, Safe, Efficacious Heparin Reversal (SBIR)

U-M Project ID: 22-PAF03485

Direct Sponsor: TSRL, Inc.

Prime Sponsor: National Institutes of Health

Principal Investigator/Department: James Morrissey, Biological Chemistry

Project Duration: One (1) Year

Funding Support: \$141,358

Purpose: The purpose of this project is to perform in vitro tests to quantify the resistance of rat plasma samples to the anticoagulant action of exogenously added heparin and conduct appropriate statistical tests with the data to determine whether meaningful conclusions can be drawn.

University Employee; University Title; Relationship with Therapeutics System Research Lab, Inc.

- Diane Nelson Hilfinger; Research Assistant II (temp), Michigan Medicine Transplant Center; Partial Owner