## 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,

Arthur Lupia

Interim Vice President for Research and Innovation

October 2024

#### Attachment A

**Direct Sponsor:** Abcon Therapeutics, Inc.

#### Project #1

STTR Phase I Subcontract Agreement between the University and Abcon Therapeutics, Inc. Reviewed by the Medical School Conflict of Interest Board		
Project Information		
<b>Title:</b> Anti-CD6, a new type of immunotherapy for triplenegative breast cancer (Abcon STTR 2.0)	U-M Project ID: 25-PAF01584	

**Prime:** National Institutes of Health

**Project Duration:** One (1) Year Funding Support: \$240,000

**Purpose:** The purpose of this project is to extend understanding of the efficacy and safety of an anti-CD6 monoclonal antibody as a novel immunotherapy for breast cancer that is resistant to other treatments.

#### University Employee; University Title; Relationship with Abcon Therapeutics, Inc.

• David Fox; Professor, Rheumatology; Partial Owner

Principal Investigator/Department: David Fox, Rheumatology

#### Project #2

SBIR Phase I Subcontract Agreement between the University and ASKO Therapeutics, Inc. Reviewed by the UMOR Conflict of Interest Review Committee		
Project Information		
<b>Title:</b> Paradigm-changing, Versatile, Scalable and Cost-effective Technology for Monthly Injections of Peptide Drugs	U-M Project ID: 24-PAF06544	
Direct Sponsor: ASKO Therapeutics, Inc.	<b>Prime:</b> National Institutes of Health	
Principal Investigator/Department: Steven Schwendeman, Pharmaceutical Sciences		
Project Duration: One (1) Year	Funding Support: \$115,000	

**Purpose:** The purpose of this project is to develop a cost-effective, extremely simple, efficient, and generalizable water-based PLGA microsphere encapsulation technology for peptide drugs.

#### University Employee; University Title; Relationship with ASKO Therapeutics, Inc.

- 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

SBIR Phase II Subcontract Agreement between the University and Blue Arbor Technologies, Inc. Reviewed by the Medical School Conflict of Interest Board

<b>Project Information</b>	
<b>Title:</b> Clinical Testing of an Advanced Neuroprosthetic Control System	U-M Project ID: 25-PAF00881
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: \$976,165

**Purpose:** The purpose of this project is to develop and test a wearable device for high fidelity prosthetic hand control.

#### University Employee; University Title; Relationship with Blue Arbor Technologies, Inc.

- Alex Vaskov; Research Fellow, Plastic Surgery; Partial Owner
- Paul Cederna; Professor, Plastic Surgery; Partial Owner
- Theodore Kung; Clinical Associate Professor, Surgery; Partial Owner

#### Project #4

STTR Phase I Subcontract Agreement between the University and Outhaul Medical Devices LLC Reviewed by the Medical School Conflict of Interest Board

Reviewed by the Medical School Conflict of Interest Board		
Project Information		
<b>Title:</b> Development of a Novel Sternal Closure Device with Improved Strength and Hemostatic Characteristics	U-M Project ID: 24-PAF06404	
Direct Sponsor: Outhaul Medical Devices LLC	<b>Prime:</b> National Institutes of Health	
Principal Investigator/Department: Alvaro Rojas-Pena, Transplant Surgery		
<b>Project Duration:</b> One (1) Year	Funding Support: \$109,898	

**Purpose:** The purpose of this project is to provide advising and consulting for all pre-clinical aspects of the production of a fully biocompatible novel sternal closure device.

## University Employee; University Title; Relationship with Outhaul Medical Devices LLC

- Jeff Plott; Research Area Specialist Senior, Cardiac Surgery; Partial Owner
- Gardner Yost; House Officer, Thoracic Surgery; Partial Owner
- Jonathan Haft; Professor, Cardiac Surgery; Partial Owner

#### Project #5

# STTR Phase I Subcontract Agreement between the University and Outhaul Medical Devices LLC Reviewed by the Medical School Conflict of Interest Board

Project Information		
<b>Title:</b> Phase I STTR/SBIR - Development of a Novel Sternal Closure Device With Improved Strength and Hemostatic Characteristics	U-M Project ID: 25-PAF01586	
Direct Sponsor: Outhaul Medical Devices LLC	Prime: National Institutes of Health	
Principal Investigator/Department: Alvaro Rojas-Pena, Transplant Surgery		

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**Project Duration:** One (1) Year Funding Support: \$121,192

**Purpose:** The purpose of this project is to provide advising and consulting for all pre-clinical aspects of the production of a fully biocompatible novel sternal closure device.

### University Employee; University Title; Relationship with Outhaul Medical Devices LLC

- Jeff Plott; Research Area Specialist Senior, Cardiac Surgery; Partial Owner
- Gardner Yost; House Officer, Thoracic Surgery; Partial Owner
- Jonathan Haft; Professor, Cardiac Surgery; Partial Owner