

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 and Innovation

October 2023

Attachment A

Project #1

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| STTR Phase I Subcontract Agreement between the University and Arcascope Inc. (formerly known as Arcascope LLC) Reviewed by the Medical School Conflict of Interest Board and the UMOR Conflict of Interest Review Committee | |
| <u>Project Information</u> | |
| Title: Feasibility of app-delivered circadian synchronization therapy in a cohort of pregnant women | U-M Project ID: 23-PAF05975 |
| Direct Sponsor: Arcascope Inc. | Prime: National Institutes of Health |
| Principal Investigator/Department: Louise O'Brien, Neurology | |
| Project Duration: One (1) Year | Funding Support: \$111,623 |
| Purpose: The purpose of this project is to adapt a prototype mobile application for iOS and Android to deliver circadian synchronization therapy with light (CST-L) to pregnant women. | |
| <u>University Employee; University Title; Relationship with Arcascope Inc.</u> | |
| <ul style="list-style-type: none">● Daniel Forger; Professor, Mathematics; Partial Owner● Olivia Walch; Adjunct Research Investigator, Neurology; Partial Owner | |

Project #2

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| Second 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 2 | U-M Project ID: 24-PAF01524 |
| 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 | |
| Current Project Duration: Two (2) Years, Two (2) Months Additional Time: One (1) Year | Current Funding Support: \$359,195 Additional Funding Support: \$19,360 |
| Purpose: The purpose of this amendment is to add additional funds and time so that 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 #3

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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): LUCIFAI: Automated Detection and Quantification of LUng Cancer screening Incidental Findings using Artificial Intelligence | U-M Project ID: 24-PAF00950 |
| 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. | |
| <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 #4

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| Amendment to Research Agreement between the University and Phenomics Health Inc. Reviewed by the Medical School Conflict of Interest Board | |
| <u>Project Information</u> | |
| New Title: Feasibility determination of retrospective clinical validation and extension of pharmacogenomics assays using patient-specific data and analytics. | U-M Project ID: 22-PAF03766 |
| Direct Sponsor: Phenomics Health Inc. | |
| Principal Investigator/Department: Brian Athey, Computational Medicine and Bioinformatics | |
| Agreement Initially Approved by the Regents: February 17, 2022 | |
| Project Duration: One (1) Year | Funding Support: \$574,886 Additional Funding Support: \$341,830 |
| Purpose: The purpose of this amendment is to add funds so that Dr. Athey may begin to lay the groundwork and build the necessary research infrastructure to create, demonstrate and evaluate a new first-generation and then second-generation neuropsychiatric pharmacogenomics (PGx) diagnostic assay for patients suffering from Major Depressive Disorder (MDD) and Treatment Resistant Depression (TRD), Generalize Anxiety Disorder (GAD), and Substance Use Disorder (SUD). | |
| <u>University Employee; University Title; Relationship with Phenomics Health Inc.</u> | |
| <ul style="list-style-type: none">• Brian Athey; Professor, Computational Medicine and Bioinformatics; Partial Owner | |