**MEMORANDUM OF UNDERSTANDING**
**BETWEEN**
**DEPARTMENT OF HEALTH AND HUMAN SERVICES**
**NATIONAL INSTITUTES OF HEALTH**
**AND**

**THE IQ CONSORTIUM**

**CONCERNING**

**Coordinated Microphysiological Systems for Drug Efficacy and Toxicity Testing in Human Health and Disease ("PROJECT").**

## I. PURPOSE

This Memorandum of Understanding (MOU) details the joint objectives of the National Institutes of Health **(NIH)** and the IQ Consortium (IQC). NCATS and IQC are referred to herein individually as a Party and collectively as the Parties. These Parties share a common interest and goal in developing novel technologies to improve drug discovery and screening methods. To that extent, this MOU will focus on further testing and development of *in vitro* microphysiological systems that represent major organs and tissues in the human body, for prediction of efficacy, bioavailability and toxicity. Each Party, operating under its own authority, intends to have specific roles in promoting this shared interest. This MOU provides a framework between NCATS and the IQC for coordination and collaborative efforts between the Parties to maintain and enhance effectiveness. It also provides the principles and procedures by which the parties involved intend to manage and share expertise and information in order to increase collaboration and strategic planning.

## II. BACKGROUND

Advances in bioengineering, such as in materials science, microfabrication, and microfluidics technologies have allowed the manufacture of microphysiological systems representing functional units of an organ that replicate physiologically the spatiotemporal, mechanical and biochemical cues inherent in those tissues. In parallel, recent developments in stem cell technology now make it possible to obtain tissues from humans with specific genotypes and/or disease phenotypes. **NIH** issued Funding Opportunity Announcements (FOA), RFA-RM-11-022 https://grants.nih.gov/grants/guide/rfa-files/RFA-RM-11-022.html; RFA-RM-12-001 https://grants.nih.gov/grants/guide/rfa-files/RFA-RM-12-001.html in order to support

research, development and deployment of human microphysiological systems. This program is called the NIH NCATS Tissue Chip Program (TC).

Adoption of microphysiological devices into the research community is an essential goal for the TC Program. Commercialization of MPS systems can be an ideal approach to disseminate the technology to the research community. In addition, insight from our regulatory colleagues has encouraged partnerships with pharmaceutical and biotechnology companies as a means to help gain validation. Furthermore, industry seeks to develop novel collaborative relationships or partnerships with the public sector that include a robust and rigorous process to jointly assess the feasibility of new technologies for drug discovery and drug screening, and thereby enable the best opportunities to be pursued. This MOU provides an excellent opportunity to bolster public-private efforts, achieve mutual benefits, and facilitate technological advancement.

## III. SCOPE

NIH and IQC intend to collaborate and coordinate efforts that will help refine microphysiological technology.

## IV. PROJECT ACTIVITIES AND RESPONSIBILITIES OF EACH PARTY

The NIH NCATS and IQC intend to assume the following respective roles and responsibilities in the PROJECT, such as:

- IQC and NIH will not exchange or transfer of funds.
- NCATS investigators are to assume respective roles and responsibilities set in the NIH FOA
- NIH intends to hold program review meetings for the program but may agree to hold joint meetings with industry partners at the same physical location and on adjacent days.
- IQC participants will be given opportunities to work directly with NIH TC investigators to provide insight and feedback for marketability of the devices along with other potential industry logistics.
- NIH TC researchers will be given opportunities to collaborate with IQC member companies regarding marketability of their devices. Separate agreements between the IQC member companies and NIH TC researchers may need to be

executed for these collaborations. Neither IQC nor NCATS is responsible for the content of these separate agreements.

Each party may utilize the expertise and relationships of the other in order to increase its own capability and responsiveness to the PROJECT.

## V. General Provisions

1. **Effective Date.** This MOU becomes effective on the date of the last signature and shall remain in full force and effect for the entire duration of the PROJECT term, unless modified or terminated.

2. **Effect of Termination.** Either Party may terminate this MOU by providing written notice to the other Party of its intent to terminate the MOU.

3. **PROJECT Activities and Responsibilities.** It is understood that the Parties that all PROJECT activities and responsibilities shall be governed by this MOU, unless the Parties agree that another type of agreement will need to be executed to complete the PROJECT.

4. **Governing Law.** This Agreement shall be governed by U.S. Federal Law as applied in the Federal Courts of the District of Columbia.

5. **Entire Agreement; Amendment.** This MOU incorporates all Exhibits and Schedules (if any) hereto and constitutes the entire agreement and understanding between the Parties in respect of the subject matter hereof and replaces in its entirety any prior discussions, negotiations, agreements or other arrangements in relation to the subject matter, whether written or oral, all of which are replaced by the terms of this MOU. No amendment or modification of this MOU shall be valid or binding unless made in writing and signed by authorized representatives of both parties.

6. **Intellectual Property.** The Parties agree that inventorship of any patentable matter, created by any of the participants pursuant to the terms of this MOU, will be determined in accordance with U.S. patent laws. Ownership will follow inventorship and vest in the inventors or their employers as determined by contract or law.

7. **Confidential Information.** The NCATS is the custodian of information that is owned by **NIH** TC researchers. NCATS will not, as part of the activities covered

by this MOU, share with other parties to the MOU or PROJECT any information that is confidential or trade secret, unless permitted to do so by the NIH TC researchers Collaborator, under a separate confidentiality agreement.

8. **Counterparts.** This MOU may be executed in counterparts, each of which shall be deemed to be an original and all of which together shall constitute a single document. The Parties acknowledge and agree that the exchange of electronic or fax signatures will have the same legal validity as the Parties' signatures would have if signed in hard copy form.

9. **Authority.** Section 479 of the Public Health Service (PHS) Act (42 U.S.C. § 287); Section 301 of the PHS Act, 42 U.S.C. § 241.

10. **Notices and Meetings.** All notices pertaining to or required by this MOU will be in writing, signed by an authorized representative of the notifying Party, and delivered by registered, certified or by an express/overnight delivery service and sent to the other Party at the address designated below.

**11. Points of Contact.** The following individuals are designated points of contact for the MOU:

The names of NIH and IQC staff listed below represent the current persons in these assigned roles at the date of signing of this MOU. Additional **NIH** staff may be drawn to provide scientific expertise on organ/tissue physiology as needed.

Scientific / Research Contacts for **NIH:**

Danilo A. Tagle, Ph.D.

NCATS/NIH

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Phone: (301) 594-8064

Email: danilo.tagle@.nih.gov

IQ Consortium Contact Name and information:

Name: Maggie Liu

Title: Science Advisor, IQ Consortium Secretariat

Address: 1500 K Street NW, Washington, DC, 20005

Email: Maggie.liu@dbr.com

Phone number: (202) 230-5677

**12. Use of Name; Public Statements.** By entering into this MOU, NCATS does not directly or indirectly endorse any product or service that is or will be provided, whether directly or indirectly related to either this MOU by IQC, its successors, assignees, or licensees. IQC will not in any way state or imply that NCATS or any of its organizational units or employees endorses any product or service. Each Party agrees to provide proposed public statements that reference or rely upon the work under this MOU to the other Party for review and comment at least seven (7) days prior to publication. Either Party may disclose the Summary Page to the public without the approval of the other Party.

***SIGNATURES BEGIN ON NEXT PAGE***

APPROVED AND ACCEPTED FOR THE NATIONAL CENTER FOR ADVANCING TRANSLATIONAL SCIENCES, NIH

By: _____
Christopher P. Austin, M.D.
Director
Date: 4/17/2015

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APPROVED AND ACCEPTED FOR IQ CONSORTIUM

By: _____
Jim Jamieson, Jr.
IQ Consortium Secretariat & Legal Counsel
Date: 4/13/15