

**MEMORANDUM OF UNDERSTANDING  
BETWEEN  
THE NATIONAL CENTER FOR ADVANCING TRANSLATIONAL SCIENCES  
OF THE NATIONAL INSTITUTES OF HEALTH (NCATS)  
AND THE CENTER FOR THE ADVANCEMENT OF SCIENCE IN SPACE (CASIS)  
ORGANIZATION  
For the**

**Coordinated Tissue Chip Systems for Drug Efficacy and Toxicity Testing in  
Human Health and Disease**

**I. PURPOSE**

This Memorandum of Understanding (MOU) sets forth a framework of partnership between the National Center for Advancing Translational Sciences (NCATS) at the National Institutes of Health (NIH) and the Center for the Advancement of Science in Space (CASIS), (collectively referred to as the “Parties”). To effectuate this purpose, the Parties hereby enter into a non-exclusive, non-binding Memorandum of Understanding.

CASIS is an IRC Section 501(c) (3) organization organized under the non-profit laws of the State of Florida whose mission is the advancement of educational and scientific research in conjunction with the International Space Station National Laboratory, and whose business address is 6905 N. Wickham Road, Suite 500, Melbourne, FL 32940.

CASIS has a cooperative agreement with NASA, No. NNH11CD70A (the “Cooperative Agreement”) pursuant to which CASIS is responsible for maximizing the value of the investment the U.S. Government has made in the International Space Station National Laboratory (“ISS NL”) and demonstrating the scientific and technological productivity of the ISS NL over the next decade.

CASIS and NCATS share a common interest and goal to find novel technologies that recapitulate human physiology and that can be used to better understand human health and disease. To that extent, this MOU will promote communication and interaction between the NIH and CASIS and other research communities, specifically in relation to the NIH NCATS Tissue Chip Program, managed by the NCATS, to facilitate space-related research and to integrate results from that research into an improved understanding of human physiology. CASIS and NCATS efforts will focus on the exchange of ideas, information, and data arising from their respective research efforts, development of biomedical research approaches and clinical technologies for use on Earth and in space, and research in Earth- and space-based facilities that could improve human health on Earth and in space. This MOU provides a framework

between NCATS and CASIS 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, microfluidics technologies and universal media 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 <http://grants.nih.gov/grants/guide/rfa-files/RFA-RM-11-022.html>; RFA-RM-12-001 <http://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.

Of particular interest is the application of the United States (U.S.) portion of the International Space Station (ISS) as a national laboratory, as established by P.L. 109-155. The designation as a National Laboratory underscores the significance and importance that the U.S. places on the scientific potential of the ISS for research in areas including, but not limited to:

- Basic biological and behavioral mechanisms in the absence of gravity.
- Human physiology and metabolism.
- Spatial orientation and cognition.
- Cell repair processes and tissue regeneration.
- Pathogen infectivity and host immunity.
- Medical countermeasures.
- Health care delivery and health monitoring technologies

The Parties have existing programs and resources for facilitating health research and technology development. Research opportunities facilitated by this MOU will be complementary to studies supported by the NIH, its Institutes and Centers, and to CASIS' mission. In pursuing objectives through this MOU, NCATS and CASIS shall handle their own activities and use their own resources, including the expenditure of their own funds unless otherwise agreed in specific implementing agreements. The

terms of this MOU and activities undertaken hereunder are not intended to nor shall they conflict, contradict, or supersede the terms of CASIS' obligations with NASA under Cooperative Agreement No. NNH11CD70A.

### **III. SCOPE**

NIH and CASIS intend to collaborate and coordinate efforts that will help refine microphysiological technology (PROJECT). This MOU does not alter existing NCATS or NIH and industry authorities, command relationships, or privacy, civil liberties, and other oversight relationships. In establishing a proposed framework to provide mutually beneficial logistical and operational support, this MOU is not intended to replicate or aggregate unnecessarily the diverse organizational structures of the NIH NCATS and CASIS in scientific research.

### **IV. PROJECT WORKPLAN AND RESPONSIBILITIES OF EACH PARTY**

The NIH NCATS and CASIS intend to assume standard respective roles and responsibilities. In addition:

- CASIS and NIH NCATS will not exchange or transfer any funds.
- NCATS and CASIS will meet recurrently to discuss technical requirements needed for Chips-in-Space, goals, milestones, business plans and other possible activities that will lead to a potential joint research initiative.
- NCATS investigators are to assume respective roles and responsibilities set in the NIH issued FOAs, RFA-RM-11-022 and RFA-RM-12-001.
- NIH NCATS intends to hold Tissue Chip Program review meetings for the program but may agree to hold joint meetings with CASIS at the same physical location and on adjacent days.
- NCATS will manage contact with CASIS and NIH NCATS Tissue Chip Investigators interested in the development of tissue chip technologies adapted for micro-gravity research.
- CASIS will communicate with any interested Tissue Chip Program Principal Investigators and/or project teams in an effort to gain a better understanding of some of the field's biggest challenges and application needs in micro-gravity research.
- NCATS and CASIS will hold at least one joint workshop at a NIH facility. NCATS will provide all necessary arrangements to support potential NIH Investigators

involvement in the workshop. CASIS will provide all necessary arrangements to support CASIS staff and relevant implementation partners' involvement in the workshop.

- CASIS and NCATS will develop business plans associated with future solicitations.
- CASIS will continue to engage NCATS in order to provide NCATS feedback on the accessibility to astronaut sample data.

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

## V. General Provisions

1. **Effect 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 between 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 MOU 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 NCATS Tissue Chip Investigators. 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 NCATS Tissue Chip Investigators, under a separate confidentiality agreement. The parties to this MOU will not disclose to any third party any nonpublic information that a party (DISCLOSING PARTY) provides to the other Party (RECEIVING PARTY), which the DISCLOSING PARTY reasonably considers to be of a confidential, proprietary or trade secret nature, including but not limited to, financial statements and projections, customer and supplier information, research, designs, plans, compilations, methods, techniques, processes, procedures, and know-how, whether in tangible or intangible form.
- 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 meaning as the Parties' signatures would have if signed in hard copy form.
- 9. Authority.** For NIH: 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 or certified mail, email or facsimile, or express/overnight delivery service and sent to the other Party at the designated in Paragraph 11.
- 11. Points of Contact.** The following individuals are designated points of contact for the MOU:

The names of NCATS and CASIS 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.  
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Email: [danilo.tagle@nih.gov](mailto:danilo.tagle@nih.gov)

CASIS Science/Technical Point of Contact:  
Michael S. Roberts, Ph.D.  
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CASIS Administrative Point of Contact:  
Sonja Kunze,  
Manager, Contracts & Compliance  
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skunze@iss-casis.org

**12. Use of Name; Press Releases.** 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 CASIS, its successors, assignees, or licensees. CASIS 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 press releases 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.

This MOU in no way restricts either Party from participating in any activity with other Public or Private agencies, organizations or individuals.

This MOU is strictly for internal management purposes for each of the Parties. This MOU shall not be construed to provide a private right or cause of action for or by any person or entity.

***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: \_\_\_\_\_

APPROVED AND ACCEPTED FOR  
CASIS

By: \_\_\_\_\_  
Gregory H. Johnson  
President & Executive Director  
Date: \_\_\_\_\_