

**COLLABORATIVE RESEARCH
AGREEMENT BETWEEN
[TC DEVELOPER INSTITUTION] AND [TCTC INSTITUTION]**

THIS COLLABORATIVE RESEARCH AGREEMENT (hereinafter “Agreement”) is entered into by and between [the Tissue Chip Developer Institution] a [Type of Entity] located at [Insert Address] hereinafter “TCD INSTITUTION”, and the Tissue Chip Testing Center Program Institution, a [Type of Entity] located at [Insert Address] hereinafter, “TCTC INSTITUTION“ for the collaborative efforts regarding tissue chip validation activities utilizing existing NIH funded Tissue Chip Developers (TCD) of tissue chip devices and related to the following NIH National Center for Advancing Translational Sciences (NCATS): Tissue Chip Testing Centers (TCTC): Validating Microphysiological Systems, **RFA-TR-16-006**.

TCD INSTITUTION’S Principal Investigator [RESEARCHER NAME], [RESEACHER ADDRESS IF DIFFERENT THAN INSTITUTION], (hereinafter “TCD RESEARCHER”) is employed by TCD INSTITUTION and has prepared a project plan (hereinafter “PROJECT PLAN” defined in 1.1) related to the NIH National Center for Advancing Translational Sciences (NCATS): Tissue Chip Testing Centers: Validating Microphysiological Systems, **RFA-TR-16-006**. TCTC INSTITUTION’S Principal Investigator [RESEARCHER NAME], [RESEACHER ADDRESS IF DIFFERENT THAN INSTITUTION], (hereinafter “TCTC RESEARCHER”) is employed by TCTC INSTITUTION.

Tissue Chip Testing Centers: Validating Microphysiological Systems

WHEREAS, TCD INSTITUTION is an awardee of an NIH GRANT (the “GRANT”) with the NIH, part of the U.S. Department of Health & Human Services, dated [INSERT DATE], the goal of GRANT is to encourage the refinement and testing of microphysiological systems, or tissue chips, and TCD INSTITUTION owns or controls specific TC technology (the “TCD INSTITUTION MATERIALS”, defined below) and data related thereto; and **WHEREAS**, TCTC INSTITUTION will utilize existing infrastructure and expertise to validate said TC devices (<https://ncats.nih.gov/files/specs-tissue-chip-validation.xlsx>) to help gain interest and support of potential stakeholders; and

WHEREAS, the studies contemplated by this Agreement will be of mutual interest and benefit to TCD INSTITUTION and TCTC INSTITUTION and the general public, and shall further the instructional and research objectives of TCTC INSTITUTION in a manner consistent with its status as a nonprofit research, education and healthcare TCTC INSTITUTION.

NOW THEREFORE, in consideration of the mutual premises and covenants set forth in this agreement and intending to be legally bound the parties hereby agree as follows:

AGREEMENT

The parties hereby agree as follows:

1. RESEARCH ACTIVITIES

- 1.1. Scope: This Agreement governs work performed in a collaborative research project described in the [RFA-TR-16-006](#) funding announcement under the **TCTC Cooperative Agreement and Milestones (hereinafter known as the PROJECT PLAN, refer to EXHIBIT A)**. This Agreement and the PROJECT PLAN shall be consistent with the terms and conditions pursuant to the application submitted in response to RFA-TR-16-006.

- 1.2. Research Activities: For the purpose of this Agreement RESEARCH ACTIVITIES means the conduct of research by the TCTC RESEARCHER towards the goals of the PROJECT PLAN. TCTC RESEARCHER'S duties will involve conducting and/or coordinating all aspects of the PROJECT PLAN.
- 1.3. TCD INSTITUTION Materials (EXHIBIT B) and Technical Support: TCD INSTITUTION agrees to provide materials and associated information as incorporated in this Agreement.

With respect to TCD INSTITUTION MATERIALS, TCTC INSTITUTION agrees to the following:

- i. TCTC INSTITUTION will use TCD INSTITUTION MATERIALS solely for the RESEARCH ACTIVITIES conducted pursuant to the PROJECT PLAN and the terms of this Agreement, and
- ii. TCTC INSTITUTION will not reverse engineer or otherwise analyze TCD INSTITUTION MATERIALS by any means, nor allow third parties to so reverse engineer or analyze TCD INSTITUTION MATERIALS on behalf of TCTC INSTITUTION. No other use of TCD INSTITUTION MATERIALS is authorized. TCTC INSTITUTION will report on and keep adequate records to show receipt, use, and disposition of all TCD INSTITUTION MATERIALS provided for the RESEARCH ACTIVITIES.
- iii. TCTC RESEARCHER agrees to receive MATERIALS from TCD RESEARCHER as described in the PROJECT PLAN solely for the purpose outlined in the PROJECT PLAN. Any and other uses or studies are expressly prohibited and may not be pursued by the TCTC RESEARCHER.
- iv. TCTC RESEARCHER shall not distribute, release, transfer, disclose, or otherwise provide access MATERIALS to any individuals or entities not a party to the Agreement without written prior consent of the TCD INSTITUTION. TCTC RESEARCHER shall refer any third party request of MATERIALS to the TCD RESEARCHER.
- v. TCTC INSTITUTION is responsible for TCD INSTITUTION MATERIALS and agrees to return all unused, explanted, or otherwise requested TCD INSTITUTION'S MATERIALS to TCD INSTITUTION upon completion of the RESEARCH ACTIVITIES. TCTC RESEARCHER maintains primary responsibility for the use and return of, all such TCD INSTITUTION MATERIALS. If applicable and reasonably requested, TCD INSTITUTION shall pay the costs of such return.
- vi. TCTC INSTITUTION recognizes that TCD INSTITUTION has a limited supply of TCD INSTITUTION MATERIALS. If milestones described in the PROJECT PLAN are not being met, TCD INSTITUTION may choose to reduce the number of systems it will provide to TCTC INSTITUTION.

Without limiting the foregoing, TCD INSTITUTION and other research staff involved in the RESEARCH ACTIVITIES as applicable will, in accordance with 21 C.F.R. 812.43(c):

- i. provide TCTC INSTITUTION with TDC RESEARCHER'S current c.v., statement of relevant experience.
- 1.4. Project Reporting: TCTC INSTITUTION will periodically provide data and written reports to TCD INSTITUTION and NIH as stated in the PROJECT PLAN

Reports and data to be provided by TCTC INSTITUTION to TCD INSTITUTION are as follows:

- i. Quarterly Progress Updates: TCTC INSTITUTION and TCD INSTITUTION will meet intermittently in accordance with the PROJECT PLAN to discuss project updates. When the parties meet for said updates, TCTC INSTITUTION will submit reports to TCD INSTITUTION and NIH in sufficient detail to demonstrate the progress of the work. These reports will include all relevant PROJECT DATA. PROJECT DATA refers to all written and otherwise recorded information created or collected in service of the PROJECT PLAN. PROJECT DATA shall include, but are not limited to, raw and analyzed data signals (e.g., physiological readouts) as well as any annotations and interpretations of the data necessary for appropriate analyses and interpretation of such PROJECT DATA. After TCD RESEARCHER receipt and review of each report, TCTC INSTITUTION will engage in a conference call with TCD INSTITUTION and NIH to discuss such report.
- ii. Final Project Report: Within six months of completion of the RESEARCH ACTIVITIES, TCTC INSTITUTION will submit a final written report summarizing the results of the research and will provide to the NIH and the TCD INSTITUTION a complete copy of PROJECT DATA, including but not limited to the raw signal records, combined with all relevant clinical annotations and interpretations resulting from this research.

2. TERM AND TERMINATION

- 2.1. Effective Dates: This Agreement is effective upon all parties' signatures and will be in effect for the term of the NIH Award and any continuation periods authorized by NIH after the final year of the award. The Agreement terminates automatically without notice upon termination and completion of final reporting of the NIH Award. The Agreement may be extended by a period of time as the parties may agree, by a written amendment to this Agreement signed by both parties.
- 2.2. Early Termination: Either party may terminate this Agreement with or without cause upon 30 days prior written notice to the other party. If this Agreement is terminated by either party or expires prior to the completion of the RESEARCH ACTIVITIES in the PROJECT PLAN, TCTC INSTITUTION will promptly provide to TCD INSTITUTION and NIH a complete copy of all PROJECT DATA through the date of termination. NIH will be notified along with explanation of the termination and may potentially adjust the PROJECT PLAN accordingly.
- 2.3. Surviving Provisions: The following provisions will survive the expiration or other termination of this Agreement as prescribed in each: CONFIDENTIALITY (Section 4), INTELLECTUAL PROPERTY (Section 5), and RESEARCHER/EDUCATIONAL AND COMMERCIAL LICENSES (Section 6) AND MISCELLANEOUS (Section 10)

3. PUBLICITY AND PUBLICATION

- 3.1. The parties agree not to use, expressly or by implication, any trademark, trade name, or any contraction, abbreviation or adaptation thereof of any other party, or the name of any other party's staff in any news, publicity release, policy recommendation, advertising, or any commercial communication without the express written approval of that party, except as required by law or by NIH for its public databases on awards, such as REPORTeR. The use of the NIH name and logo or that of its components must be cleared according to the NIH Notice of Grant Award.
- 3.2. TCTC RESEARCHER and TCD RESEARCHER may, at their discretion, publish the results of activities performed under this Agreement if both parties agree. Both TCTC RESEARCHER/INSTITUTION and TCD RESEARCHER/INSTITUTION must comply with this paragraph such that publication(s) in a peer-reviewed scientific journal article or abstracts or

presentation(s) made at a scientific meeting (“Publication”) will not violate the confidentiality terms of the Agreement.

- i. Should publishing be contemplated, involved parties will review the draft for confidential information at least 45 calendar days prior to submittal for publication or presentation. A final draft will be provided to all involved parties for review at least 10 business days prior to submittal for publication or presentation, if a draft of the same was previously submitted and reviewed by TCD INSTITUTION; otherwise, TCD INSTITUTION will have 30 calendar days to review prior to submittal for publication or presentation.
- ii. All Publications shall include (a) a statement disclosing contributions of involved parties to the RESEARCH ACTIVITIES, and (b) disclosure of any third party (e.g. medical writer) contribution (authorship or contributorship) according to the International Committee of Medical Journal Editors (ICMJE) requirements for disclosure in publications and/or the journal specific requirements.
- iii. TCD INSTITUTION will limit its review to: determine whether TCD INSTITUTION CONFIDENTIAL INFORMATION (defined in 4.1) is disclosed, allow TCD INSTITUTION to protect its rights in patentable or copyrightable material, and to correct or adjust, if necessary, any descriptions or characterizations of TCD INSTITUTION MATERIALS. TCD INSTITUTION will not attempt to censor or in any way interfere with presentation or conclusions beyond the extent necessary to protect TCD INSTITUTION CONFIDENTIAL INFORMATION or to ensure that TCD INSTITUTION MATERIALS are accurately described.
- iv. When reasonably requested by TCD INSTITUTION and TCTC INSTITUTION will delay publication up to an additional 45 days to allow TCD INSTITUTION to protect its rights in patentable or copyrightable material. At TCD INSTITUTION’S request, TCTC RESEARCHER/INSTITUTION agree to remove any TCD INSTITUTION CONFIDENTIAL INFORMATION contained in the Publication and to correct any incorrect TCD INSTITUTION information. If available, TCD INSTITUTION will identify and supply a substitute for any TCD INSTITUTION CONFIDENTIAL INFORMATION.

3.3. Ownership of copyright in any Publication by TCTC RESEARCHER/INSTITUTION relating to the RESEARCH ACTIVITIES that is prepared in accordance with Section 3.2 will vest in TCTC RESEARCHER/INSTITUTION or as otherwise required by the publisher. To the extent possible and subject to the rights of the publisher of any such Publication and any federal applicable laws, TCTC INSTITUTION hereby grants to TCD INSTITUTION a worldwide, unlimited, perpetual, and royalty-free nonexclusive license to use, reproduce, and distribute such copyrightable work. TCTC INSTITUTION agrees to sign and deliver to TCD INSTITUTION any documents required to secure TCD INSTITUTION’S rights under this paragraph.

4. CONFIDENTIALITY

4.1. TCD INSTITUTION CONFIDENTIAL INFORMATION means any information acquired TCTC INSTITUTION from TCD INSTITUTION that:

- i. is identified as confidential at the time of disclosure by TCD INSTITUTION to TCTC INSTITUTION, or within a reasonable time after such disclosure; or
- ii. TCTC INSTITUTION has a reasonable basis to believe is confidential.

- 4.2. TCTC INSTITUTION, except as required by law or a court of competent jurisdiction, will keep the TCD INSTITUTION'S CONFIDENTIAL INFORMATION secret and confidential and will take all reasonable precautions to protect the TCD INSTITUTION CONFIDENTIAL INFORMATION from disclosure as though such TCD INSTITUTION CONFIDENTIAL INFORMATION were TCTC INSTITUTION'S to protect. TCTC INSTITUTION will not use or exploit the TCD INSTITUTION CONFIDENTIAL INFORMATION for the benefit the TCTC INSTITUTION or any third party other than to use the TCD INSTITUTION CONFIDENTIAL INFORMATION for the conduct of the RESEARCH ACTIVITIES under this Agreement, as specifically authorized by TCD NSTITUTION in writing, or as required by law or a court of competent jurisdiction. Any disclosure of TCD INSTITUTION CONFIDENTIAL INFORMATION by TCTC INSTITUTION to TCTC INSTITUTION'S employees or contractors will be only to those who have a need to know the TCD INSTITUTION CONFIDENTIAL INFORMATION. To the extent necessary to protect TCD RESEARCHER'S rights, TCTC INSTITUTION must have and continue to maintain appropriate written agreements with its employees or contractors engaged in the RESEARCH ACTIVITIES sufficient to enable them to comply with this Agreement. To the extent permitted by state law, TCTC INSTITUTION is responsible for any disclosure of TCD INSTITUTION'S CONFIDENTIAL INFORMATION by its employees or contractors other than pursuant to this Agreement.
- 4.3. TCD INSTITUTION CONFIDENTIAL INFORMATION does not include information:
- i. after it becomes publicly available through no fault of TCTC INSTITUTION;
 - ii. that is lawfully obtained from third parties who are under no restriction of disclosure; or
 - iii. that can be shown as evidenced in writing to be previously known or developed by TCTC INSTITUTION independently of TCD INSTITUTION.
- 4.4. All TCD INSTITUTION CONFIDENTIAL INFORMATION remains the property of TCD INSTITUTION. Nothing in this Agreement will be deemed to grant TCTC INSTITUTION any license to TCD INSTITUTION'S intellectual property except as may be necessary for TCTC INSTITUTION to use the TCD INSTITUTION MATERIALS or TCD INSTITUTION SUPPORT for the RESEARCH ACTIVITIES.
- 4.5. In the event that, on the advice of legal counsel, TCTC INSTITUTION is compelled by law to disclose TCD INSTITUTION CONFIDENTIAL INFORMATION, TCTC INSTITUTION will notify TCD INSTITUTION in advance of such disclosure about the need for, and the exact text of, any such disclosure so that TCD INSTITUTION may seek a protective order or other remedy. TCTC INSTITUTION will cooperate with TCD INSTITUTION, if requested, in seeking such protective order or other remedy. TCTC INSTITUTION will take every reasonable action to ensure protection of the disclosed TCD INSTITUTION CONFIDENTIAL INFORMATION to the extent allowable by law. Notwithstanding the above, the parties acknowledge that TCTC INSTITUTION may disclose upon request the name of the TCTC research team, the title and short description of the RESEARCH ACTIVITY, the amount and source of funding, grant number or research support, if applicable, without prior approval of TCD INSTITUTION.
- 4.6. TCTC INSTITUTION may not copy or duplicate any materials containing TCD INSTITUTION CONFIDENTIAL INFORMATION except as necessary to accomplish the purposes of this Agreement. TCTC INSTITUTION will return, at TCD INSTITUTION'S expense if reasonably requested, or will destroy all materials containing TCD INSTITUTION CONFIDENTIAL INFORMATION, including all copies, upon demand by TCD RESEARCHER, provided that TCTC INSTITUTION may retain one secure copy as may be required by law or to fulfill any continuing obligations under this Agreement.
- 4.7. The restrictions and obligations assumed by TCTC INSTITUTION and by TCD INSTITUTION under this section expire five (5) years from the expiration of this Agreement, except that to the extent any Trade Secrets are included in the TCD INSTITUTION CONFIDENTIAL INFORMATION, such

restrictions and obligations will continue for the longest time permitted by law, so long as such Trade Secrets qualify as Trade Secrets under applicable law.

- 4.8. TCTC INSTITUTION CONFIDENTIAL INFORMATION means any information acquired by TCD INSTITUTION from TCTC INSTITUTION that;
- i. identified as confidential at the time of disclosure by TCTC INSTITUTION to TCD RESEARCHER, or within a reasonable time after such disclosure; or
 - ii. TCD INSTITUTION has a reasonable basis to believe is confidential
- 4.9. TCD INSTITUTION, except as required by law or a court of competent jurisdiction, will keep the TCTC INSTITUTION CONFIDENTIAL INFORMATION secret and confidential and will take all reasonable precautions to protect the TCTC INSTITUTION CONFIDENTIAL INFORMATION from disclosure as though such TCTC INSTITUTION CONFIDENTIAL INFORMATION were TCD RESEARCHER'S to protect. TCD INSTITUTION will not use or exploit the TCTC INSTITUTION CONFIDENTIAL INFORMATION for the benefit of TCD INSTITUTION or any third party other than to use the TCTC INSTITUTION'S CONFIDENTIAL INFORMATION for the conduct of the RESEARCH ACTIVITIES under this Agreement, as specifically authorized by the TCTC INSTITUTION in writing, or as required by law or a court of competent jurisdiction. Any disclosure of TCTC INSTITUTION CONFIDENTIAL INFORMATION by TCD RESEARCHER, through its employees or contractors will be only to those who have a need to know the TCTC INSTITUTION CONFIDENTIAL INFORMATION. To the extent necessary to protect TCTC INSTITUTION'S rights, TCD INSTITUTION must have and continue to maintain appropriate written agreements with its employees or contractors engaged in the RESEARCH ACTIVITIES sufficient to enable them to comply with this Agreement. To the extent permitted by state law, TCD INSTITUTION is responsible for any disclosure of TCTC INSTITUTION'S CONFIDENTIAL INFORMATION by its employees or contractors other than pursuant to this Agreement.
- 4.10. TCTC INSTITUTION CONFIDENTIAL INFORMATION does not include information:
- i. after it becomes publicly available through no fault of TCD RESEARCHER
 - ii. that is lawfully obtained from third parties who are under no restriction of disclosure; or
 - iii. that can be shown as evidenced in writing to be previously known or developed by TCD INSTITUTION independently of the TCTC INSTITUTION.
- 4.11. All TCTC INSTITUTION CONFIDENTIAL INFORMATION remains the property of TCTC INSTITUTION. Nothing in this Agreement will be deemed to grant TCD INSTITUTION any license to TCTC INSTITUTION'S intellectual property except as may be necessary for TCD INSTITUTION in the support of the RESEARCH ACTIVITIES.
- 4.12. In the event that, on the advice of legal counsel, TCD INSTITUTION is compelled by law to disclose TCTC INSTITUTION'S CONFIDENTIAL INFORMATION, TCD INSTITUTION will notify TCTC INSTITUTION in advance of such disclosure about the need for, and the exact text of, any such disclosure so that TCTC INSTITUTION may seek a protective order or other remedy. TCD INSTITUTION will cooperate with TCTC INSTITUTION if requested, in seeking such protective order or other remedy. TCD INSTITUTION will take every reasonable action to ensure protection of the disclosed TCTC INSTITUTION CONFIDENTIAL INFORMATION. TCD INSTITUTION may disclose upon request the name of the TCTC research team and their associated TCTC INSTITUTION, the title and short description of the RESEARCH ACTIVITY, and the amount and source of funding or research support, if applicable, without prior approval of TCTC INSTITUTION.

- 4.13. TCD INSTITUTION may not copy or duplicate any materials containing TCTC INSTITUTION'S CONFIDENTIAL INFORMATION except as necessary to accomplish the purposes of this Agreement. Upon request TCD INSTITUTION will return, at TCTC INSTITUTION'S expense if reasonably requested, or will destroy all materials containing TCTC INSTITUTION'S CONFIDENTIAL INFORMATION, including all copies, upon demand by TCTC INSTITUTION, provided that TCD INSTITUTION may retain one secure copy as may be required by law or to fulfill any continuing obligations under this Agreement.
- 4.14. The restrictions and obligations assumed by TCTC INSTITUTION and by TCD INSTITUTION under this section expire five (5) years from the expiration of this Agreement, except that to the extent any Trade Secrets are included in the TCTC INSTITUTION'S CONFIDENTIAL INFORMATION, such restrictions and obligations will continue for the longest time permitted by law, so long as such Trade Secrets qualify as Trade Secrets under applicable law.

5. INTELLECTUAL PROPERTY

- 5.1. All rights, title and interest in and to any INVENTIONS or technologies of TCTC INSTITUTION or of TCD RESEARCHER, respectively, existing on or before the Effective Date of this agreement, and all rights, title and interest in and to any concept, information, invention or technologies developed by TCTC INSTITUTION or TCD INSTITUTION outside the Program hereunder (altogether, the "BACKGROUND INTELLECTUAL PROPERTY") shall be the exclusive property of the respective party.
- 5.2. Ownership of new intellectual property arising out of the RESEARCH ACTIVITIES (and the Patents, if any, which claim such new intellectual property) shall be determined according to inventorship as defined under U.S. patent law at the time the INVENTION is made, i.e.:
- 5.2.1. Shall belong to TCTC INSTITUTION, if the inventors are one or more collaborator(s) of TCTC INSTITUTION and none of the inventors are collaborator(s) of TCD INSTITUTION ("TCTC INSTITUTION INVENTION"),
- 5.2.2. Shall belong jointly to TCTC INSTITUTION and TCD INSTITUTION, if the inventors are one or more collaborator(s) of TCTC INSTITUTION and one or more collaborator(s) of TCD INSTITUTION ("JOINT INVENTION"),
- 5.2.3. Shall belong to TCD RESEARCHER, if the inventors are one or more collaborator(s) of TCD INSTITUTION and none of the inventors are collaborator(s) of TCTC INSTITUTION ("TCD INSTITUTION INVENTION").
- 5.3. TCTC INSTITUTION and TCD INSTITUTION will each disclose to the other Party all inventions discovered under this Agreement and owned by the disclosing Party promptly after becoming aware of such inventions.
- 5.4. Patents on TCTC INSTITUTION INVENTIONS. TCTC INSTITUTION shall have the right to file patent applications covering any TCTC INSTITUTION INVENTION. TCTC INSTITUTION shall give TCD INSTITUTION written notice of its intent to file such patent applications at least forty-five (45) days in advance of the intended filing date, and TCD INSTITUTION shall have the right to review all patent applications on TCTC INSTITUTION INVENTIONS and provide TCTC INSTITUTION with comments.
- 5.5. Patents on TCD INSTITUTION INVENTIONS. TCD INSTITUTION shall have the right to file patent applications covering any TCD INSTITUTION INVENTION. TCD INSTITUTION shall be solely

responsible for the prosecution and maintenance of all Patent applications and Patents claiming TCD INSTITUTION INVENTIONS and all costs related thereto.

- 5.6. Patents on Joint INVENTIONS. TCTC INSTITUTION and TCD INSTITUTION shall confer regarding the filing of patent applications on JOINT INVENTIONS. Subject to the grant of licenses herein and the exercise of the option under Section 6.6, each Party shall be free to exploit, either itself or through the grant of licenses to Third Parties (which Third Party licenses may be further sublicensed), rights in any JOINT INVENTIONS, including any patents directed thereto, throughout the world without restriction, without the need to obtain further consent from or provide notice to the other party, and without any duty to account or otherwise make any payment of any compensation to the other party.
- 5.7. Each Party undertakes on behalf of itself, its directors, officers, employees, AFFILIATE and permitted subcontractors to do such further acts and execute such documents as may be reasonably necessary to give effect to each Party's rights under this Section 5. "AFFILIATE" means any company, body or other organization directly or indirectly controlling, controlled by, or under common control with a Party to this Agreement where "control" is defined as the direct or indirect holding of a majority of the stock entitled to vote (or other voting interest) or to otherwise appoint and remove the management of the company, body or organization.
- 5.8. It is understood with respect to patent filing, prosecution or maintenance activities conducted by each Party with respect to any Joint INVENTIONS arising under this agreement, that each Party is represented by its own counsel. Neither Party, nor any of its AFFILIATES or sub-licensees, nor any of their employees or agents shall be liable for any act or omission with respect to such activities.

6. RESEARCH/EDUCATIONAL AND COMMERCIAL LICENSES

- 6.1. TCTC INSTITUTION grants to TCD INSTITUTION and TCD INSTITUTION'S AFFILIATES, for internal research and development purposes only, a non-exclusive, world-wide, perpetual, non-cancelable, royalty-free, fully paid-up license under TCTC INSTITUTION'S rights in TECHNICAL DEVELOPMENTS ("TECHNICAL DEVELOPMENTS" means any invention, discovery, composition, enhancement, technology, advancement, know how, data, device, machine, material, software or any other information arising from the PROJECT PLAN, including any such development protectable by patent, copyright, or other protection under law), including its rights in TCTC INSTITUTION INVENTIONS and Patents covering such TCTC INSTITUTION'S INVENTIONS. The foregoing license shall be without the right to transfer or grant sublicenses to any third party (except to contractors performing work solely for the benefit of TCD INSTITUTION and its AFFILIATES and under obligations of confidentiality and non-use similar to those of this Agreement), unless TCD INSTITUTION receives the express written permission of TCTC INSTITUTION to do so.
- 6.2. TCD INSTITUTION grants to TCTC INSTITUTION and TCTC INSTITUTION'S AFFILIATES, for internal research and development purposes only, a non-exclusive, world-wide, perpetual, non-cancelable, royalty-free, fully paid-up license under TCD INSTITUTION'S rights in Technical Developments, including its rights in TCD INSTITUTION INVENTIONS and Patents covering such TCD INSTITUTION INVENTIONS, to use the TECHNICAL DEVELOPMENTS for internal research and educational purposes only. The foregoing license shall be without the right to transfer or grant sublicenses to any third party (except to contractors performing work solely for the benefit of TCTC INSTITUTION or its AFFILIATES and under obligations of confidentiality and non-use similar to those of this Agreement), unless TCTC INSTITUTION receives the express written permission of TCD INSTITUTION.
- 6.3. TCD INSTITUTION grants to TCTC INSTITUTION and its AFFILIATES a non-exclusive, world-wide, royalty-free, fully-paid license (without the right to transfer or grant sublicenses) during the Term under TCD INSTITUTION'S rights in MATERIALS (EXHIBIT B) provided by TCD INSTITUTION to TCTC

INSTITUTION under the PROJECT PLAN to use such MATERIALS under the PROJECT PLAN.

- 6.4. TCTC INSTITUTION grants to TCD INSTITUTION and its AFFILIATES a non-exclusive, world-wide, royalty-free, fully-paid license (without the right to transfer or grant sublicenses) during the Term under TCTC INSTITUTION 's rights in MATERIALS (EXHIBIT B) provided by TCTC INSTITUTION to TCD INSTITUTION under the PROJECT PLAN to use such MATERIALS under the PROJECT PLAN.
- 6.5. TCTC INSTITUTION represents and warrants that (a) TCTC INSTITUTION has and will have the full right to license the TCTC INSTITUTION OR JOINTLY DEVELOPED INTELLECTUAL PROPERTY, free from all claims, liens, security interests, or other encumbrances, and (b) all employees and contractors engaged in the PROJECT PLAN for TCTC INSTITUTION are and will be able, bound and have the right to assign such TCTC RESEARCHER'S INVENTIONS OR JOINT INVENTIONS, free from all claims, liens, security interests or other encumbrances.

TCD INSTITUTION represents and warrants that (a) TCD INSTITUTION has and will have the full right to license the TCD INSTITUTION OR JOINTLY INVENTION, free from all claims, liens, security interests, or other encumbrances, and (b) all employees and contractors engaged in the PROJECT PLAN for TCD INSTITUTION are and will be able, bound and have the right to assign such TCD RESEARCHER'S INVENTIONS OR JOINT INVENTIONS, free from all claims, liens, security interests or other encumbrances.

- 6.6. TCTC INSTITUTION hereby grants to TCD INSTITUTION the exclusive option to acquire a worldwide, royalty-bearing, exclusive or non-exclusive license, including the right to grant sublicenses under an exclusive commercial license, to make, use, sell, offer for sale, import and export Products, under all of TCTC INSTITUTION'S right, title and interest in TCTC INSTITUTION Technical Developments, including Patents covering any of the foregoing which arise from the work performed under that PROJECT PLAN. TCD INSTITUTION and its AFFILIATES must exercise the Option by providing written notice to TCTC INSTITUTION within six (6) months after written notification by TCTC INSTITUTION to TCD INSTITUTION of the corresponding TECHNICAL DEVELOPMENT of INVENTION or within six (6) months of completion of the PROJECT PLAN under which the TECHNICAL DEVELOPMENT OR INVENTION arose, whichever is later, *provided, however*, that if CTC INSTITUTION gives notice to TCD INSTITUTION of its intent to file a patent application under **Section 5.4** and if TCD INSTITUTION does not request TCTC INSTITUTION to file the patent application in any specific countries, then the Option will expire six (6) months from the date TCTC INSTITUTION first notifies TCD INSTITUTION of TCTC INSTITUTION 's intent to file the patent application. TCD INSTITUTION'S failure to timely exercise such option shall cause such option to lapse and expire. In the event that TCTC INSTITUTION and TCD INSTITUTION are not able to agree to terms for such license or assignment within 180 days from TCD RESEARCHER's exercise of such opportunity, TCTC INSTITUTION shall be free to negotiate with any third party for rights to the PATENT RIGHTS. For two (2) years following TCTC INSTITUTION'S disclosure to TCD INSTITUTION PATENT RIGHTS, TCTC INSTITUTION shall not offer to any third party better terms than were offered to TCD INSTITUTION.
- 6.7. Consideration terms for any license elected pursuant to the Option shall specifically include, but will not be limited to, provisions that:

[Specific financial terms mutually agreeable to the Parties to be inserted here].

- 6.8. Additional License Terms.

- 6.8.1. Each exclusive license agreement granting rights from TCTC INSTITUTION to TCD INSTITUTION and which results from TCD RESEARCHER's exercise of the Option will contain a provision requiring TCD INSTITUTION to use Commercially Reasonable Efforts to commercialize a Product or a service (as applicable) in the United States and other countries if

mutually agreed to by TCTC INSTITUTION and TCD INSTITUTION.

6.8.2. TCTC INSTITUTION will have the right under all circumstances to grant a license for TCTC INSTITUTION TECHNICAL DEVELOPMENTS to not-for-profit research institutions and the United States Government to use TCTC INSTITUTION TECHNICAL DEVELOPMENTS for research and teaching purposes only and not for use in the manufacture, distribution or sale of products. Nothing herein shall affect the United States Government's rights under the Bayh Dole Act, including the Government license under 35 U.S.C. § 202.

6.9. TCD INSTITUTION grants to TCTC INSTITUTION the right to use PROJECT DATA for all noncommercial, research and educational, and for publications purposes under the terms of this Agreement.

6.9.1. Data/Information Ownership and Disclosure: TCD INSTITUTION will own PROJECT DATA and relevant reports provided by TCTC INSTITUTION, and may use them for any purpose in accordance with applicable laws, provided, however, that TCD INSTITUTION shall not publicly disclose information derived from the PROJECT DATA or contained in such reports until TCTC INSTITUTION has published such information pursuant to Section 3.2, except as needed in regulatory and patent filings in the United States and all other countries and regions, or with the prior written permission of TCTC INSTITUTION. However, if PROJECT DATA are not submitted for publication within one (1) year after completion of the RESEARCH ACTIVITIES or termination of this Agreement, TCD INSTITUTION has the have the right to use the data and reports for any purpose without TCTC INSTITUTION'S approval. Similarly, if a publication is not released within 2 years after completion of the RESEARCH ACTIVITIES or termination of this Agreement, TCD INSTITUTION will have the right to use the data and reports for any purpose without TCTC INSTITUTION'S approval. If TCD INSTITUTION uses PROJECT DATA in a publication TCD INSTITUTION shall follow the third party (e.g. medical writer) contribution (authorship or contributorship) guidelines according to the International Committee of Medical Journal Editors (ICMJE) requirements for disclosure in publications and/or the journal specific requirements.

7. INDEPENDENT CONTRACTOR

7.1 TCTC INSTITUTION is an independent contractor for all purposes. Neither the TCTC INSTITUTION nor any agent, representative, contractor nor employee of the TCTC INSTITUTION will be considered an agent, representative or employee of TCD INSTITUTION for any purpose including, but not limited to, workers' compensation insurance, unemployment insurance, social security insurance, federal, provincial and state taxes and TCD INSTITUTION employee benefits and coverages.

7.2 TCD INSTITUTION is an independent contractor for all purposes. Neither the TCD INSTITUTION, nor any agent, representative, contractor nor employee of the TCD INSTITUTION will be considered an agent, representative or employee of the TCTC INSTITUTION for any purpose including, but not limited to, workers' compensation insurance, unemployment insurance, social security insurance, federal, provincial and state taxes and TCTC INSTITUTION employee benefits and coverages.

7.3 Conduct and control of the work to be performed under this Agreement by TCTC INSTITUTION lies solely with TCTC INSTITUTION, and TCTC INSTITUTION shall exercise reasonable diligence in conducting and completing the PROJECT PLAN.

7.4 TCTC INSTITUTION may not incur any liability on TCD INSTITUTION'S behalf nor bind TCD INSTITUTION to any contractual or payment obligation without the prior written consent of TCD INSTITUTION.

8. REPRESENTATIONS AND COVENANTS

- 8.1. TCTC INSTITUTION represents that all of its employees, agents, contractors and consultants whose services may be used to perform RESEARCH ACTIVITIES in accordance with this Agreement, or otherwise fulfill the obligations under this Agreement, are or will be appropriately informed of the terms of this Agreement, and that all such persons are under legal obligation to TCTC INSTITUTION, by contract or otherwise, sufficient to fully comply with this Agreement.
- 8.2. TCTC INSTITUTION represents that it has and will have full right and authority to enter into this Agreement under applicable law, including its internal rules and that, where and whenever required, TCTC INSTITUTION will secure in a timely manner, any and all necessary notifications or approvals, administrative or governmental, including authorizations from any medical TCTC INSTITUTION s where the RESEARCH ACTIVITIES are to be performed in whole or in part.
- 8.3. TCTC INSTITUTION represents that TCTC INSTITUTION does not have any outstanding obligations or agreements that would interfere with or undermine the execution of this Agreement or performance of the PROJECT PLAN.
- 8.4. TCTC INSTITUTION, on behalf of TCTC RESEARCHER, represents that TCTC RESEARCHER has not participated in a clinical investigation or other research activity that has been terminated by any regulatory or governmental authority, hospital review board or ethics committee, or the sponsor of such activities, due to TCTC RESEARCHER's non-compliance with any applicable laws, rules, regulations or protocol requirements.
- 8.5. Neither Party, nor any of its personnel involved in this Agreement, including AFFILIATES, agents, and contractors are presently subject to debarment or suspension by any agency of the Government. Should either Party or any of its personnel involved in this Agreement be debarred or suspended during the term of this Agreement, the Parties agree to notify each other and the NIH within thirty (30) days of receipt of final notice.

9. PROJECT ADVISORY COMMITTEE AND PRIMARY PROJECT CONTACTS

All negotiations and contracting related to TCTC INSTITUTION INVENTIONS or JOINT INVENTIONS shall be conducted through:

[INSERT TCTC INSTITUTION and INSTITUTIONAL OFFICE NAME]

And

[INSERT TCD INSTITUTION RESEARCHER and TCD INSTITUTIONAL OFFICE NAME].

- 9.1. Responsibilities of PRIMARY CONTACTS from TCD INSTITUTION and TCTC INSTITUTION:
 - i. The PRIMARY CONTACTS will communicate and coordinate day-to-day decisions regarding RESEARCH ACTIVITIES and other project-related issues, except those issues that are expressly designated as the responsibility of other individuals or offices as explicitly described in this Agreement.
 - ii. The PRIMARY CONTACTS will bear overall accountability to their respective organizations for the conduct of the RESEARCH ACTIVITIES under the PROJECT PLAN.
- 9.2. Replacement of PRIMARY CONTACT. Each party's PRIMARY CONTACT may only be replaced by the written agreement of the other party, such agreement not to be unreasonably withheld or delayed. Each party may remove or replace other members of the PROJECT ADVISORY COMMITTEE at will.

10. MISCELLANEOUS

- 10.1. This Agreement supersedes all prior oral agreements and understandings between the parties with respect to the activities under this Agreement. No amendments, changes, extensions, modifications to, or waivers of this Agreement shall be valid and binding except if in writing and signed by the parties, except that either party may change its address by written notice to the other. No waiver by either party of any default of the other party will be held to be a waiver of any other or subsequent default. This Agreement may be signed in one or more copies, including facsimile, each of which equally evidences this Agreement. This Agreement may be executed in one or more counterparts, all of which are considered one and the same agreement, and will become a binding agreement when one or more counterparts have been signed by each party and delivered to the other party.
- 10.2. In the event that any provision contained in this Agreement is held to be invalid or unenforceable, all other provisions of this Agreement shall be deemed severable and shall remain enforceable to the full extent permitted by law. Should the terms of this Agreement and that of any associated protocol or Project Plan conflict, this Agreement shall supersede and prevail. Nothing in this Agreement may be construed to conflict with or supersede the rights and requirements of the NIH under the terms and conditions of the NIH Award or by operation of law or regulation.
- 10.3. No Warranty: Any information, results, materials, services, resources, intellectual property or other property or rights granted, granted access to, or provided by TCD INSTITUTION to TCTC INSTITUTION pursuant to this Agreement, including TCD INSTITUTION MATERIALS and TCD INSTITUTION SUPPORT, are on an “as is” basis. Except as may otherwise be affirmatively stated in the PROJECT PLAN, TCD INSTITUTION makes no warranties of any kind, either expressed or implied, as to any matter including, but not limited to, warranty of fitness for particular purpose, merchantability, exclusivity, accuracy, integration, or results obtained from intellectual property, including but not limited to, any use of any intellectual property made or created under the Agreement, nor shall TCD INSTITUTION be liable to TCTC INSTITUTION for indirect, special, or consequential damages including, but not limited to, loss of profits or inability to use, use properly, or use without errors, said intellectual property or any applications and derivations thereof. TCD INSTITUTION makes no warranties of any kind with respect to freedom from patent, trademark, or copyright infringement, informational content, accuracy, integration, or theft of trade secrets and does not assume any liability hereunder for any infringement of any patent, trademark, or copyright arising from the use of the intellectual property or rights granted or provided by it hereunder. TCTC INSTITUTION agree that they will not make any warranty on behalf of TCD INSTITUTION expressed or implied, to any person concerning the application of, accuracy of, or the results to be obtained with the intellectual property, or with respect to any other matter.
- 10.4. All references to TCD INSTITUTION shall include [INSERT PARENT TCD INSTITUTION AND/OR AFFILIATES INCLUDED IN THIS AGREEMENT]. All references to TCTC INSTITUTION mean the [INSERT TCTC INSTITUTION INFORMATION], which is governed under the laws of the State of [INSERT STATE].

TCTC INSTITUTION may not assign its rights or obligations under this Agreement absent prior written approval from TCD RESEARCHER.

Notices. Notices to be given under this Agreement shall be in writing and sent to the parties as follows:

If to TCD INSTITUTION, to:
[INSERT CONTACT AND ADDRESS]

With copy to:
[INSERT CONTACT AND ADDRESS]

If to TCTC INSTITUTION," to:
[INSERT CONTACT AND ADDRESS]

With copy to:
[INSERT CONTACT AND ADDRESS]

Any such notice will be validly given if delivered in person, by certified mail, return receipt requested, by courier or by confirmed facsimile transmission, and shall be deemed effective on receipt.

Changes to any terms or conditions of this Agreement or to the PROJECT PLAN which are requested by NIH, must be approved by TCD INSTITUTION and TCTC INSTITUTION in writing before they are effective.

This Agreement shall remain silent on the issue of governing law.

The parties hereto have executed two (2) duplicate originals in the manner appropriate to each.

SIGNATURES BEGIN ON NEXT PAGE

TCD INSTITUTION

TCTC INSTITUTION

By: _____

By: _____

Print Name: _____

Print Name: _____

Title: _____

Title: _____

Date: _____

Date: _____

READ AND ACKNOWLEDGED BY:
<TCD RESEARCHER, NAME AND TITLE>

READ AND ACKNOWLEDGED BY:
<TCTC RESEARCHER, NAME AND TITLE>

By: _____

By: _____

Date: _____

Date: _____

**EXHIBIT A
PROJECT PLAN**

PROJECT PLAN to be jointly developed by the Tissue Chip Testing Center and Tissue Chip Developer; to be inserted in EXHIBIT A

**EXHIBIT B
TCD INSTITUTION MATERIALS**

TCD INSTITUTION list of materials provided to TCTC INSTITUTION will be listed and described below and inserted as EXHIBIT B