

## **CONSORTIUM MEMBER AGREEMENT**

### **Agreement between the Medical Technology Enterprise Consortium “MTEC” and its Members**

#### **Concerning**

Support of the U.S. Army Medical Research and Development Command “USAMRDC” and its research, development, and follow-on production efforts under an Other Transactions Agreement for Prototyping (*Agreement Number: W81XWH-15-9-0001*) as established between the MTEC and USAMRDC, U.S. Army Medical Research Acquisition Activity.

Effective Date: October 2, 2015

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Notifications filed with DOJ and FTC pursuant to the National Cooperative Research and Production Act of 1993 (15 U.S.C. 4301).

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## CONSORTIUM MEMBER AGREEMENT

### PREAMBLE

This Consortium Member Agreement (the “Agreement”) is dated as of the 2nd day of October, 2015, as amended, by and between the Medical Technology Enterprise Consortium referred to herein as “MTEC” or the “Consortium,” and the Consortium Members (as defined herein).

### WITNESSED

**WHEREAS**, MTEC has entered into an Other Transactions Agreement (the “OT Agreement” or “OTA”) with the U.S. Army Medical Research and Development Command “USAMRDC” for funding certain research and development leading to technology demonstrations and deployment, independently or in partnership with the USAMRDC, to develop and produce new U.S. Food and Drug Administration (FDA)-approved vaccines, biologics, drugs, medical software, devices and procedures to protect, treat, and optimize the health and performance of the U.S. military personnel;

**WHEREAS**, the Consortium Members wish to ensure quick and efficient delivery of critical medical technologies to enhance the capabilities of the U.S. Government and its departments and agencies through military biomedical research, product design, process engineering, prototyping and testing (laboratory, animals and humans) for select vaccine, biologics, drug, medical software and device programs;

**WHEREAS**, the Consortium Members concurrently wish to develop, sustain and expand their collective strategic technical superiority in developing and producing new FDA-approved vaccines, biologics, drugs, medical software, devices and products;

**WHEREAS**, the Consortium Members wish to develop, execute and sustain a flexible, multi-year Research, Development and Technology Program clearly defining performance goals, and maximizing the collective capabilities of Government, industry and academia to focus those capabilities toward attaining sound mission technology solutions;

**WHEREAS**, the Consortium Members wish to provide a unified and coordinated message to the Government’s Legislative Branch and Executive Departments (e.g., Defense, Health and Human Services, Homeland Security, Energy, etc.) regarding the strategically important role biomedical technology will play in current and future systems development;

**WHEREAS**, the Consortium Members wish to define programs and obtain program funding that is focused on adapting, developing, demonstrating and transitioning mission-critical technologies in support of national goals and objectives to protect, treat and optimize the health and performance of U.S. military personnel;

**WHEREAS**, MTEC and the Consortium Members are entering into this Agreement in order to (a) support the establishment and growth of MTEC as a consortium to conduct biomedical research, development and technology programs, (b) transition requirements from research to production and commercialization, (c) adapt commercial developments to new requirements from the Government, (d) provide for their respective rights and obligations as Consortium Members, and (e) provide guidance with respect to other matters involving the activities conducted by Consortium Members.

**NOW, THEREFORE,** in consideration of the foregoing and the mutual covenants and promises contained in this Agreement, the Consortium Members agree as follows:

## **ARTICLE I –DEFINITIONS**

**1.1** When used in this Agreement, the following terms, whether used in the singular or plural, shall have the meanings set forth herein.

**1.2** “Additional Consortium Members” means the Consortium Members who become signatories or otherwise join as a party to this Agreement after the Effective Date pursuant to the procedures set forth herein and in OT Agreement(s) between the Consortium and the USAMRAA.

**1.3** “Affiliate” means, with respect to a specified Consortium Member that is a signatory to this Agreement, any university, company, partnership, joint venture and/or firm which now or hereafter controls, is controlled by or is under common control with such specified Consortium Member. For purposes of this definition, "control" shall mean (i) in the case of corporate entities, direct or indirect ownership of at least 50% of the stock or shares entitled to vote for the election of directors; and (ii) in the case of non-corporate entities, direct or indirect ownership of at least 50% of the equity interest with the power to direct the management and policies of such non-corporate entities.

**1.4** “Agreement” means this Consortium Member Agreement.

**1.5** “Committees” means the committees established by the Consortium in coordination with the Government as soon as practical after the effective date of the OTA to receive guidance, develop/recommend research initiatives, identify educational and training programs, interface with key Government organizations to identify emerging technology needs, and discuss Government intellectual property opportunities and member products and innovations that may be of interest to the Government. The committees will have membership and leadership from the Consortium Members and shall be established not later than ninety (90) days after the OT Agreement effective date.

**1.6** “Consortium Member Agreement” means this Agreement governing the rights and obligations of the Consortium Members as they relate to MTEC and to each other.

**1.7** “Consortium Member” or “Consortium Members” means the individual organizations that are or become signatories to this Agreement either as Consortium Members or as Additional Consortium Members.

**1.8** “Department of Defense (DoD) Component” means the Office of the Secretary and its subordinate organizations and laboratories and the Department of the Army, the Department of the Navy, the Department of the Air Force and their respective commands and laboratories.

**1.9** “Effective Date” means the date first written above and on which this Agreement was approved by the MTEC Board.

**1.10** “Field” means the field of biomedical sciences and related fields as applied to maintaining and improving service member health and performance in diverse environments.

**1.11** “Government” means the United States of America, herein represented by the U.S.

Army Medical Research and Development Command (USAMRDC) and/or the U.S. Army Medical Research Acquisition Activity (USAMRAA).

**1.12** “MTEC” or “Consortium” has the meaning set forth in the first paragraph of this Agreement.

**1.13** “Member in Good Standing” means being current (no greater than 45 days past due) on membership dues and current (no greater than 90 days past due) on research project award assessments.

**1.14** “MTEC Base Agreement” means the agreement between MTEC and the Consortium Member organization or a team of Consortium Member entities, under the terms of the OT Agreement between the MTEC and the Government, which serves as the baseline agreement for all future MTEC Research Project Awards. The MTEC Base Agreement, among other things, flows down applicable terms and conditions from the OTA.

**1.15** “MTEC Research Project Awards” refers to agreements issued by MTEC, or an entity authorized by MTEC, under the terms of a MTEC Base Agreement, for executing a specific MTEC research project.

**1.16** “Other Government Agencies” means the Department of Energy (DOE), Department of Health and Human Services (DHHS), Department of Homeland Security (DHS), and other non-defense agencies of the U.S. Government.

## **ARTICLE II –THE CONSORTIUM**

**2.1 Background.** The Government has expressed a desire to establish an enterprise partnership with an industry and academia consortium to facilitate research and development activities, in cooperation with USAMRDC and Other Government Agencies, in the biomedical sciences (including but not limited to drugs, biologics, vaccines, medical software and medical devices) to protect, treat and optimize the health and performance of U.S. military personnel. In response to the Government’s desire, MTEC was formed as a nonprofit corporation, incorporated under the laws of the State of South Carolina with the following principal objectives:

- (a) biomedical research and prototyping;
- (b) exploration of private sector technology opportunities;
- (c) technology transfer; and
- (d) deployment of intellectual property and follow-on production.

It is anticipated that the MTEC entity will contract with the Government using an OTA authorized under 10 USC 2371b, as amended. Through this OTA, the Government, MTEC and the Consortium Members will conduct research and development activities that advance the state-of-the-art as well as medical science and technology skills in the fields that are needed to develop and transition new and improved medical technologies to support current and future U.S. military personnel health needs.

**2.2 Consortium Member Agreement.** This Agreement between the Consortium and

Consortium Members shall govern the relationships and interaction between the Consortium and Consortium Members, and among the Consortium Members. All Consortium Members must meet the basic requirements outlined in Article III of this Agreement. Membership is further contingent upon prospective members agreeing to this agreement and signing the Consortium Membership Application.

**2.3 Objectives of the Consortium.** The following are the specific objectives of the collaborative effort between the Members and the Government:

- (a) Research and prototyping to support USAMRDC requirements;
- (b) Exploration of promising private sector technology opportunities, to include investing in small companies that are developing promising technologies, drugs and biologics;
- (c) Providing funding for critical studies that may attract other investors;
- (d) Deployment of Government intellectual property;
- (e) Procurement and production of military stocks, to include additional testing and modification needed to meet military requirements; and
- (f) Pursuit of funds from foundations, financially sound strategic partners and investors in furtherance of the MTEC mission and objectives.

**2.4 Scope of the Research Effort.** The following are examples of the biomedical areas of the collaborative efforts between the MTEC, Consortium Members and the Government:

- (a) Military Infectious Diseases – Discover disease causing microorganisms and develop vaccines/drugs to prevent and treat infectious diseases rapidly.
- (b) Combat Casualty Care – Reduce the killed-in-action rate of U.S. military personnel, reduce the morbidity of combat injuries, and reduce the medical footprint on the battlefield by providing biologics, pharmaceuticals and devices that enhance the capability of the medical staff in effectively treating casualties as close to the location and time of injury as possible.
- (c) Military Operational Medicine – Develop effective countermeasures against stressors and maximize health, performance and fitness. This includes injury prevention and reduction, psychological health and resilience, and environmental health and protection.
- (d) Clinical and Rehabilitative Medicine – Develop technologies and products to replace or regenerate human cells, tissues or organs to restore or establish normal functions, such as tissue regeneration, bone scaffolding, and stem cell-enabled treatments for severely injured service members.
- (e) Advanced Medical Technologies – Develop initiatives and products that will increase medical mobility while ensuring access to essential medical expertise and support, regardless of the operating environment. Efforts include e-health, digital warrior, hospital of the future integrative medicine, advanced orthopedic devices and

treatments, advanced medical imaging technologies, robotic technologies to treat and rescue battlefield casualties, nanotechnology and biomaterials for diagnosis and therapy, technologies for treating neurological injuries, and regenerative medicine.

- (f) Medical Simulation and Information Sciences – Develop products and processes that increase patient safety and quality of care through simulation-based technologies and health informatics systems, including developing products and processes that implement or improve medical simulation and training, health informatics and mobile health, and decision support tools and physiological models.

The Government may provide specific technical objectives from time-to-time.

**2.5 Benefits of Consortium Membership.** MTEC has been organized and will be operated to provide the following benefits to member organizations:

- (a) Consortium members will have access to information concerning Government technology requirements which may not be available to non-members. In addition to promoting information exchange with Government attendees at MTEC general membership meetings, MTEC officers and staff will work to foster discussions between the Government and consortium members on a case-by-case basis.
- (b) The MTEC officers and staff will provide a forum for conducting emerging technology discussions among member organizations, and report the results of such discussions back to the Government to help shape the requirements the Government may publish in a subsequent research announcement.
- (c) USAMRDC and other federal agencies may use the OTA vehicle to fund certain research and development programs. Only consortium members will be eligible to bid and receive awards for such programs funded through the OTA.
- (d) The MTEC management team will facilitate interactions between and among consortium members so that proposals can be more collaborative and more closely aligned with specific Government requirements. Such collaboration should increase the potential for an award.
- (e) The MTEC management team will engage industry to gain a better understanding of their metrics for the technology areas being funded, thereby presenting a research target for consortium members that would facilitate greater technology transfer opportunities.
- (f) The MTEC management team will maintain access to regulatory and clinical specialties that can assist start-up members in their research program development.
- (g) The MTEC management team will maintain access to intellectual property rights professionals who could assist in licensing agreements and royalty valuation as desired by consortium members.

## **ARTICLE III – CONSORTIUM MANAGEMENT AND ADMINISTRATION**

**3.1 Organization and Administration.** MTEC is organized and administered as a non-profit corporation in the State of South Carolina. Subject to the provisions of the MTEC Articles of

Incorporation and Bylaws, the business and affairs of the Corporation shall be managed by the MTEC Board of Directors (hereinafter MTEC Board). The MTEC Board has the authority to make and alter the MTEC Bylaws and to elect a President and other officers of the consortium who will carry out the orders, resolutions and other executive, supervisory and management functions as authorized by the MTEC Board.

**3.1.1** The MTEC Board may establish an Executive Committee.

**3.1.2** The MTEC Board may authorize and establish additional committees of the MTEC Board with such powers and duties as may be deemed necessary and advisable in conducting the business activities and affairs of MTEC. Such committees, if formed and so authorized by the MTEC Board, will work in conjunction with USAMRDC to identify, improve and expand synergies for rapidly developing and transitioning critically needed (and cost-effective) technology in the Field. Membership on such committees shall be governed by the MTEC Bylaws.

**3.2 Consortium Membership Requirements.** Membership in the Consortium shall be granted to qualified firms and institutions organized or existing under the laws of the United States, its territories, and possessions operating in the disciplines of biomedical technology outlined in Article II. Membership eligibility for non-U.S. organizations is discussed in Article 3.2.2 below. The MTEC Chief Operating Officer (COO), or his/her designee, shall determine whether an applicant is eligible for membership, and must approve the application. Consortium Members must comply with this Agreement, the MTEC Base Agreement and all applicable federal laws, rules and regulations. The membership application and approval process will be open to prospective members throughout the year. The Consortium Membership Application is available on the MTEC website ([www.mtec-sc.org](http://www.mtec-sc.org)).

The MTEC COO, or his/her designee, will maintain a current membership list and will make it available on a Consortium website as additional members join the Consortium. The Consortium will be open to and include Members from industry, academic research institutions, and non-profit and not-for-profit organizations. MTEC adopts a non-exclusive, open membership policy. The Consortium will recruit additional Members in accordance with the provisions contained in this Agreement and in the OTA. The MTEC COO, or his/her designee, will notify the Government of the addition or deletion of Members. Any Member, regardless of when they join the MTEC, shall enjoy the same rights and incur the same obligations as any other Member hereunder.

All members in good standing are eligible for nomination to the MTEC Board of Directors and/or Committees established by the MTEC Board subject to and in accordance with the MTEC Bylaws.

Each Consortium Member shall have only such rights as may be expressly set forth in this Agreement. Notwithstanding anything in this Agreement to the contrary, no Consortium Member shall be a "member" as that term is defined or used in the South Carolina Nonprofit Corporation Act of 1994, as amended, and no Consortium Member shall have any of the rights granted to members pursuant to the South Carolina Nonprofit Corporation Act of 1994, as amended, including, but not limited to, the right to elect directors.

**3.2.1 Multi-Member Organizations.** Multi-member organizations such as medical consortia,



foundations, industry trade associations, and others are eligible for membership in MTEC. For the purposes of this section, there are two types of multi-member organizations, as described below.

(a) A multi-member organization may be a single entity that serves as an information broker for its constituents to assist them in identifying opportunities and needs, but does not submit proposals under its own entity moniker. Membership for such organizations entitles the multi-member organization to participate in MTEC activities (general membership meetings, receive research announcements, etc.), but does not entitle the organization to receive any research project award funding. Individual members of these multi-member organizations must themselves be MTEC members in order to propose against research announcements or receive awards under those announcements.

(b) Multi-member organizations capable of conducting their own research and development activities shall be subject to the same membership eligibility requirements and dues structure as the single organization entities described in paragraph 3.2 above.

**3.2.2 Foreign Organizations.** Membership eligibility for any agency or instrumentality of a foreign government and firms, institutions or business organizations which are owned or substantially controlled by foreign governments, shall be decided on a case-by-case basis at the sole discretion of the MTEC Board.

**3.3 Membership Dues.** Membership in the MTEC will become effective upon submission of the Consortium Membership Application and payment of the initial dues assessment. MTEC Members will pay annual dues in the amounts as follows: \$5,000 for large businesses, \$1,000 for all other single organization entities (small businesses, academic research institutions, and not-for-profits), and \$500 for multi-member organizations that are not capable of conducting their own research and development operations. On a case-by-case basis, the President may consider a request to waive all or part of the dues for very small, innovative organizations, particularly those that qualify as non-traditional government contractors. MTEC Members will pay annual dues every January 1st. New Members will pay pro-rated dues payable upon initial acceptance of membership and then \$5,000, \$1,000 or \$500 respectively per year every January 1<sup>st</sup> thereafter. The pro-rated dues structure, based upon the date of initial application acceptance, is as follows:

(a) Large Business:

- (1) January through December: \$5,000
- (2) April through June: \$3,750
- (3) July through September: \$2,500
- (4) October through December: \$1,250

(b) All other single organization entities (includes multi-member organizations capable of conducting their own research and development operations per paragraph 3.2.1 above:

- (1) January through December: \$1,000
- (2) April through June: \$750
- (3) July through September: \$500
- (4) October through December: \$250

(c) Multi-member organizations that cannot conduct their own research and development operations per paragraph 3.2.1 above:

- (1) January through December: \$500
- (2) April through June: \$375
- (3) July through September: \$250
- (4) October through December: \$125

The U.S. Small Business Administration (SBA) size standards will be used to determine business size. Small business size standards define the largest that a business concern, including all of its affiliates, may be and yet qualify as a small business concern for SBA and most other federal programs. The SBA has established two widely used size standards – 500 employees for most manufacturing and \$7.5 million in average annual receipts for many non-manufacturing industries.

The MTEC Board may adjust the membership dues structure from time to time to sustain the Consortium's ability to balance its revenues and expenses.

**3.4 Research Project Award Assessments.** In addition to any initial and annual dues that all MTEC Members are required to pay, each recipient of a research project award under the OTA shall pay MTEC an amount equal to two percent (2.0%) of the total funded value of each research project award. Such deposits shall be due not later than ninety (90) days after the research project award. Members who have not paid the assessment or dues within ninety (90) days of the due date are not "Members in good standing" for additional research project awards, or for participation in general or committee meetings or otherwise until the delinquency is cured.

The MTEC Board may adjust the assessment percentage from time to time to sustain the Consortium's ability to balance its revenues and expenses.

**3.5 Membership Meetings and Meeting Attendance.** General annual meetings of the Consortium membership will be held in locations designated by the MTEC in coordination with the USAMRDC. The purpose of these meetings is to bring together Consortium Members and Government research directors so that (1) the technical requirements of the Government may be presented, (2) the Consortium Members may network and form teams to respond to the Government's requirements with innovative ideas, solutions and technologies, and (3) other business may be conducted, as appropriate. Special meetings of the Members, for any purpose or purposes, may be called at any time by the MTEC President. Attendance at general and special meetings is not mandatory, but all Consortium Members are encouraged to attend.

3.6 **Consortium Member Voting Rights.** Each Consortium Member shall be entitled to one vote on each matter submitted to a vote of the Consortium Members. Only Members in good standing may vote.

3.7 **Consortium Member Affiliates.** Regardless of the number of Affiliates, a Consortium Member with one or more Affiliates participating in MTEC is considered to be one Consortium Member.

3.8 **Members Bound by Agreement.** MTEC and the Consortium Members agree to be bound by the terms of this Agreement and the MTEC Base Agreement.

3.9 **Consortium Member Right to Withdraw.** Notwithstanding the foregoing, any Consortium Member shall have the right to withdraw pursuant to Article VI of this Agreement, Withdrawal of Consortium Members.

3.10 **Consortium Information Sharing.** Consortium Members agree they will not sell, rent, or lease information provided on the MTEC Members Only site, or use it for non-membership purposes.

#### **ARTICLE IV – PROPRIETARY INFORMATION**

All members must agree to comply with the MTEC Proprietary Information Exchange Agreement as a condition for membership. The Proprietary Information Exchange Agreement is attached as Exhibit A.

#### **ARTICLE V – EXPORT CONTROLS**

##### **5.1 Export Controls.**

The Members shall comply with all applicable export control laws and regulations of the United States, including the Arms Export Control Act (“AECA”), the International Traffic in Arms Regulations (“ITAR”), the Export Administration Regulations (“EAR”), and other U.S. government directives related to export control. No Member shall export or re-export any information, data, technical know-how, products, goods or related services (“Controlled Items”) under this Agreement in violation of the AECA, ITAR or EAR. No Member shall disseminate any Controlled Item to a foreign person (as defined in the ITAR), or to persons and affiliated entities of foreign governments, foreign government agencies or foreign organizations, under this Agreement in violation of the AECA, ITAR or EAR. No Member shall disseminate any Controlled Item to any person or affiliated entity of a person or entity named on the U.S. Department of Treasury Denied Parties List, the U. S. Department of Commerce Unverified List, the U. S. Department of Commerce Entity List or any other U.S. government list of persons or entities under this Agreement to which dissemination of Controlled Items shall not be made.

#### **ARTICLE VI – WITHDRAWAL OF CONSORTIUM MEMBERS**

6.1 **Voluntary Withdrawal.** A Consortium Member may voluntarily withdraw from this Agreement at any time and for any or for no reason by notice of withdrawal given by such Consortium Member to the MTEC and the other Consortium Members in accordance with

paragraph 12.7.

**6.2 Involuntary Withdrawal.** If a Consortium Member materially breaches any material warranty, term, or condition of this Agreement, and fails to remedy such material breach within thirty (30) days or as mutually agreed after receipt of notice of such material breach from another Consortium Member and/or the MTEC, the Consortium shall have the right to cause the involuntary withdrawal of such Consortium Member, such withdrawal to be effective immediately upon delivery of a notice from the MTEC to such Consortium Member indicating their election to cause such involuntary withdrawal to occur.

**6.3 Effect of Withdrawal.**

**6.3.1 Rights of a Consortium Member.** Except for the rights and obligations pursuant to specific intellectual property agreements between or amongst the Consortium Members, from and after the effective date of withdrawal of a Consortium Member, such Consortium Member shall cease to have any rights or obligations as a Consortium Member under this Agreement except for outlined in the Proprietary Information Exchange Agreement (Exhibit A).

**6.3.2 Continued Funding and Technology Contribution Commitment.** In the event of the withdrawal of a Consortium Member pursuant to this Article, such Consortium Member's rights and obligations pursuant to any executed MTEC Research Project Awards, including but not limited to, continued funding and technology contribution commitments shall continue in accordance with the specific terms and schedule of the MTEC Research Project Award under the MTEC Base Agreement to completion or until the Government, MTEC, and the Consortium Member come to agreement to terminate the Agreement, whichever is first. Should a Consortium Member receiving an award under the MTEC Base Agreement for a multi-year program of work withdraw its membership after such award, the withdrawing Member shall receive no funding beyond the program year in which the withdrawal of membership occurs.

## **ARTICLE VII – TERM, RENEWAL, AND TERMINATION**

**7.1 Term.** This Agreement shall continue for a period of ten (10) years from the date of execution by MTEC.

**7.2 Renewal.** Not later than the end of the ninth year of the OT Agreement, MTEC shall notify the Consortium Members of its intent to renew the term of this Agreement for an additional ten (10) years. MTEC and those Consortium Members agreeing to such a renewal shall enter into an appropriate amendment of this Agreement reflecting the terms to be in effect during the renewal period.

**7.3 Termination of Agreement.** Except for the rights, obligations, and commitments of the individual or collective Consortium Members with respect to cash, royalties, profit sharing or "in-kind" contributions required by specific MTEC Research Project Awards issued under the MTEC Base Agreement, and/or specific intellectual property agreements between or amongst the Consortium Members and/or the Government, unless extended by mutual written agreement of the parties thereto, this Agreement shall automatically terminate under the following conditions:

- (a) By written agreement of MTEC and the Consortium Members;

- (b) After the Government's failure to extend an applicable OT Agreement or issue a new OT Agreement to MTEC within ninety (90) days after the expiration or termination of the applicable OT Agreement.

**7.4 Material Breach or Default by a Consortium Member.** If a Consortium Member is alleged to have breached any material warranty, term, or condition of this Agreement, the MTEC Board of Directors shall review the facts of the alleged material breach or default and determine whether the Consortium Member has, in fact, committed such a material breach. Upon such determination that a breach has occurred, the MTEC shall notify the offending Consortium Member in accordance with the provisions of paragraph 12.7. If the Consortium Member fails to remedy such material breach within thirty (30) days or as mutually agreed after receipt of such notice of such material breach from the MTEC, the MTEC may, at its option, and in addition to any other remedies that MTEC may have in law or equity, terminate this Agreement with respect to such Consortium Member by sending a notice of termination to such Consortium Member, which will also constitute notice of involuntary withdrawal pursuant to Article VI.

**7.5 Survival.** Notwithstanding the above provisions, each Consortium Member's rights and obligations with respect to Article IV and/or specific intellectual property agreements by and between the Consortium and the Consortium Member(s) shall survive any expiration or termination of this Agreement.

## **ARTICLE VIII – REPRESENTATIONS AND WARRANTIES**

**8.1 Representations and Warranties of All Parties.** Each Consortium Member represents and warrants to the other Consortium Members that: (a) it is free to enter into this Agreement; (b) in so doing, it will not violate any other agreement to which it is a party; and (c) it has taken all action necessary to authorize the execution and delivery of this Agreement and the performance of its obligations under this Agreement.

## **ARTICLE IX – LIMITATION AND CROSS-WAIVER OF LIABILITY**

**9.1 Waiver of Liability.** Consortium Members waive all claims against MTEC and against any of the entities or persons that are Consortium Members based on alleged damages relating to and arising out of activities under this Agreement. Notwithstanding the foregoing, this waiver shall not apply to claims or damages arising from or related to Article IV.

**9.2 Inapplicability.** Notwithstanding the other provisions of this article, this waiver of liability shall not be applicable to:

- (a) Claims between a Consortium Member and its related entities;
- (b) Claims made by a natural person, his/her estate, survivors, or subrogates for injury or death of such natural person;
- (c) Claims for damage caused by willful misconduct; or
- (d) Intellectual property claims.

**9.3 Disclaimer.** While MTEC members are encouraged to take advantage of the ecosystem that membership provides, which may include entering into various agreements and business relationships with other members, such parties are solely responsible for any agreement or business relationship they make. MTEC makes no, and hereby disclaims all warranties or representations, express or implied, either in fact or by operation of law, by statute or otherwise, relating to agreements and business relationship that organizations may make with each other as a result of their membership or participation in MTEC activities.

**9.4 Limitation of Liability.** In no event will any party hereto be liable for any special, incidental, consequential, or indirect damages arising in any way out of this Agreement, however caused and on any theory of liability. This limitation will apply whether or not the other party or parties hereto have been advised of the possibility of such damage. Nothing in this Article shall be construed to create the basis of a claim or suit where none would otherwise exist.

## **ARTICLE X – DISPUTE RESOLUTION**

**10.1. Dispute Resolution Process.** The Consortium and Consortium Members recognize that disputes regarding certain matters may from time to time arise during the term of this Agreement, which relate to the Consortium and Consortium Members rights and/or obligations hereunder or thereunder. It is the objective of the Consortium and Consortium Members to establish procedures to facilitate the resolution of disputes arising under this Agreement in an expedient manner by mutual cooperation and without resort to litigation. To accomplish this objective, the Consortium Members agree to follow the procedures set forth in this Article if and when a dispute arises under this Agreement. However, if an organization can provide evidence that it is prohibited from entering into binding arbitration, the dispute resolution procedures will consist of Sections 10.2 and 10.5 below.

**10.2 Dispute Resolution Representatives.** In the event of disputes between the Consortium and Consortium Members, or among the Consortium Members, the Consortium or Consortium Member or Members seeking to resolve such dispute will, by written notice to the other, have such dispute referred to their respective executive officers designated below or their successors, for attempted resolution by good faith negotiations within fourteen (14) days after such notice is received. The designated officers are as follows:

For a Consortium Member: Designated Senior Executive

For the Consortium: Designated MTEC Officer

In the event the designated officers are not able to resolve the dispute, either Party may at any time after the fourteen (14)-day period invoke the provisions of paragraph 10.3 hereinafter.

**10.3 Alternative Dispute Resolution (ADR).** Following settlement efforts pursuant to paragraph 10.2, any dispute, controversy, or claim arising out of or relating to the validity, construction, enforceability, or performance of this Agreement, including disputes relating to alleged breach or termination of this Agreement, other than disputes which are expressly prohibited herein from being resolved by this mechanism, shall be settled by binding Alternative Dispute Resolution (ADR) in the manner described below:

**10.3.1 ADR Request.** If the Consortium or Consortium Member or Members hereafter identified as parties, intend to begin an ADR to resolve a dispute, such party shall provide written notice (the ADR Request) to the other party informing such other party of such intention and the issues to be resolved. From the date of the ADR Request and until such time as any matter has been finally settled by ADR, the running of the time periods regarding the subject matter of the dispute contained in Article VI under which a party must cure a breach of this Agreement shall be suspended.

**10.3.2 Additional Issues.** Within ten (10) business days after the receipt of the ADR Request, the other party may, by written notice to the party initiating the ADR, add additional issues to be resolved.

**10.3.3 No ADR of Intellectual Property or Patent Issues.** Disputes regarding the ownership of, and/or rights to intellectual property, including the scope, validity and enforceability of patents, shall not be subject to the ADR provision in this Article, but rather submitted to a court of competent jurisdiction.

**10.4 Arbitration Procedure.** Any dispute or claim arising out of or in connection with this Agreement shall be finally settled by binding arbitration in accordance with the then current rules and procedures of the American Arbitration Association. The arbitration shall be conducted by three (3) arbitrators having experience with the issue under consideration, one (1) each to be appointed by the parties in dispute and a third nominated by the two (2) arbitrators so selected or, if they cannot agree on a third arbitrator, by the President of the American Arbitration Association. Such arbitration will take place at a location agreeable to the Members who are parties to the dispute.

The arbitrators shall apply the law of the state in which the dispute arose to the merits of any dispute or claim, without reference to rules of conflicts of laws. Judgment on any award rendered by the arbitrators may be entered in any court having jurisdiction thereof. The parties agree that, any provision of applicable law notwithstanding, they will not request, and the arbitrators shall have no authority to award punitive or exemplary damages against any party. Nothing in this Article shall limit a party's right to seek injunctive relief with respect to a breach or threatened breach of this Agreement.

**10.5 Dispute Resolution for Governmental Entities.** Recognizing that many state agencies (e.g., institutions of higher education) cannot accept the binding arbitration procedure as delineated in Sections 10.3 and 10.4 above due to state law prohibitions, the dispute resolution process for these entities will be as follows:

At any time, if a dispute cannot be resolved amicably between both parties, either party may seek alternative forms of dispute resolution, such as mediation or non-binding arbitration, under circumstances agreed upon by the parties or by a court of competent jurisdiction. Each party shall bear its own cost of such dispute resolution, and both shall proceed diligently with performance of services until the dispute is resolved. Notwithstanding the above, both parties shall have available all remedies in law or in equity.

## **ARTICLE XI – COMPLIANCE WITH ANTITRUST LAWS**

MTEC members shall comply with U.S. antitrust laws in connection with all MTEC-related activities. The MTEC Board of Directors will make a copy of applicable antitrust compliance guidelines available to all members.

## **ARTICLE XII – GENERAL PROVISIONS**

**12.1 Independent Contractors.** The relationship of MTEC and the Consortium Members established by this Agreement is that of independent contractors, and nothing contained in this Agreement shall be construed to (i) give any of the parties hereto the power to direct or control the day-to-day activities of another party hereto, (ii) constitute the parties hereto as partners, joint ventures, co-owners or otherwise as participants in a joint or common undertaking, or (iii) allow any of the parties hereto to create, discharge, or assume any obligation on behalf of another party hereto for any purpose whatsoever.

**12.2 Parties Bound.** This Agreement shall be binding upon and inure to the benefit of MTEC and the Consortium Members, their respective successors, assigned legal representatives and heirs.

**12.3 Assignment.** This Agreement may not be assigned or transferred by a Consortium Member without the prior written consent of MTEC; provided, however, that a Consortium Member may assign its rights and delegate its obligations (i) to any affiliate of such Consortium Member (although, in the event of any such assignment and delegation, the assigning Consortium Member shall remain primarily liable for its obligations hereunder) and (ii) to a purchaser of all or substantially all of the business to which this Agreement relates of such Consortium Member by merger, sale of assets or otherwise. If the Consortium Member, after the assignment or purchase, cannot meet the requirements for Consortium Membership as set forth herein, the Consortium Member will be considered to have voluntarily withdrawn from the Consortium in accordance with Article VI hereof.

**12.4 Affiliates.** The parties hereto acknowledge and agree that Consortium Members may elect to carry out certain activities required or permitted pursuant to this Agreement by or through their Affiliates. This Agreement shall be binding on the Affiliates of Consortium Members in accordance with the terms of this Agreement as if such Affiliates were parties to this Agreement.

**12.5 Entire Agreement.** This Agreement, and the attached Exhibit A constitute the entire and only agreement between MTEC and the Consortium Members relating to the subject matter hereof, and all prior negotiations, representations, agreements and understandings are superseded hereby.

**12.6 Further Assurances.** At any time, or from time to time after the date of this Agreement, a Consortium Member shall, at the request of MTEC or any Consortium Member, (i) execute, and deliver or cause to be delivered, all such assignments, consents, documents or further instruments of transfer or license, and (ii) take or cause to be taken all such other actions, as any Consortium Member may reasonably deem necessary or desirable in order for the



Consortium Member to obtain benefits of this Agreement and the transactions contemplated hereby to which the Consortium Member may be entitled.

**12.7 Notices.** Any notice or other communication required or permitted under this Agreement shall be in writing and (i) personally delivered; (ii) mailed, postage prepaid, first class, certified mail, return receipt requested; (iii) sent, shipping prepaid, return receipt requested by national overnight courier service; or (iv) sent by electronic mail. Any notice or other communication given by personal delivery shall be deemed given on the date personally delivered; any notice or other communication given by mail shall be deemed given five (5) days after the date deposited in the United States mail; any notice or other communication given by national overnight courier service shall be deemed given on the next business day after being sent; and any notice given by electronic mail shall be deemed given on the day sent.

**12.8 Amendments.** No amendment or modification of this Agreement shall be valid unless approved by the MTEC Board and executed by MTEC. Any amendment or modification so approved and executed shall be binding on all parties hereto, including any party who objects to or votes against such amendment in a referral to the membership in accordance with the following sentence. The MTEC Board may, at its discretion, but shall not be required to, refer certain proposed amendments to the full MTEC membership for validation by a majority vote of the membership (but no such validation shall be required, even when a proposed amendment is so referred). In the event that a Member is unable or unwilling to accept amendments to this Agreement, such Member may withdraw from the Consortium in accordance with Article VI. All proposed amendments to this Agreement shall be distributed to the MTEC Board Members at least thirty (30) days prior to the proposed effective date.

**12.9 Waiver.** No waiver of any rights shall be effective unless assented to in writing by the party waiving such rights, and the waiver of any breach or default shall not constitute a waiver of any other right hereunder or any subsequent breach or default.

**12.10 Section Headings.** The headings of the several sections of this Agreement are intended for convenience of reference only and are not intended to be a part of, or to affect the meaning or interpretation of this Agreement.

**12.11 Severability.** In the event that any provision of this Agreement becomes or is declared by a court of competent jurisdiction to be illegal, unenforceable or void, this Agreement shall continue in full force and effect without said provision; provided that no such severance of any provision shall be effective if the result of such materially changes intended purposes of this Agreement to the parties.

**12.12 Counterparts.** This Agreement may be executed in counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. All Consortium Members shall receive a copy of this executed Agreement and any amendments thereto, with originals to be retained by MTEC.

**12.13 No Third Party Beneficiary Rights.** MTEC and the Consortium Members agree and acknowledge that the Government is not intended to be, and shall not constitute, a third-party beneficiary of this Agreement, which is intended exclusively as an agreement among, and for

the benefit of MTEC and the Consortium Members.

**12.14 Force Majeure.** No failure or omission by MTEC or the Consortium Members in the performance of any obligation of this Agreement shall be deemed a breach of this Agreement or create any liability if the same shall arise from any cause or causes beyond their control, including, but not limited to, the following: acts of God; acts or omissions of any Government; any rules, regulations or orders issued by any Governmental authority or by any officer, department, agency or instrumentality thereof; fire; storm; flood; earthquake; accident; war; rebellion; insurrection; riot; and invasion and provided that such failure or omission resulting from one of the above causes is cured as soon as is practicable after the occurrence of one or more of the above-mentioned causes.

**12.15 Order of Precedence.** In the event of any inconsistency between the terms of this Agreement and the terms set forth in the MTEC Base Agreement, the inconsistency shall be resolved by giving precedence in the following order: (1) the MTEC Research Project Award and applicable Statements of Work, drawings and specifications, (2) the MTEC Base Agreement, and (3) this Agreement.

**12.16 Business Development.** MTEC intends to engage in business development activity on behalf of its Consortium Members. The purpose of such business development is to expand MTEC's visibility and availability to the Government, and to expand membership in the Consortium by traditional and non-traditional businesses and academia. MTEC intends to facilitate the transition of technology developed by small, non-traditional or academic Consortium Members to demonstrate prototypes and achieve FDA approval, follow-on production, and ultimately commercialization.

**Exhibits:**

Exhibit A      Proprietary Information Exchange Agreement

## **EXHIBIT A: PROPRIETARY INFORMATION EXCHANGE AGREEMENT**

1. During the term of this Consortium Member Agreement, the Members of the Medical Technology Enterprise Consortium agree that they may exchange confidential or proprietary information (“Confidential Information”) with Members having a need to know, for the purpose of furthering the goals of the Medical Technology Enterprise Consortium as defined in the Agreement. Confidential Information is defined as all confidential and proprietary information disclosed by a Member to another Member or other Members including, without limitation, information regarding existing and future technical, business and marketing plans and product strategies; cost and pricing information; employees’ names, titles, job descriptions and salaries; business practices, policies, methodologies and procedures; proprietary data, data models, product designs, capabilities, specifications, program code, and software systems and processes; samples and devices; demonstrations; and/or other proprietary and/or competition sensitive information. Confidential Information also includes the identity of and the confidential and/or proprietary information of a Member’s subsidiaries, affiliated companies, business partners, customers, potential customers and suppliers. The initial effective date of this Proprietary Information Exchange Agreement (“Agreement”) shall be the effective date of this Consortium Member Agreement, as amended. Thereafter, this Agreement shall be effective for any new Members to the Consortium Member Agreement on the date such new Member signs the Medical Technology Enterprise Consortium Membership Application.

2. Notwithstanding that the term of this Agreement will have expired after a period of ten (10) years from receipt, each Member agrees to keep in confidence and prevent the use (except for the purposes of this Agreement) or the disclosure to any person or persons outside the receiving Member’s organization, and limit the disclosure inside its organization to employees having a need-to-know, of all Confidential Information received under this Agreement (provided such Confidential Information is marked with a confidential or proprietary legend by the disclosing Member). The Members shall take every reasonable effort to keep properly-marked “Confidential Information” confidential. In order to be protected hereunder, data which is (i) in written form shall be clearly labeled as confidential or proprietary and receiving Members shall have no obligation regarding information which is not so labeled, and (ii) first disclosed orally or by demonstration must be identified as proprietary or confidential at the time of disclosure, and shall be reduced to writing or other tangible form, and marked as “Confidential Information,” within thirty (30) days after such disclosure

or demonstration. All protection and restrictions as to use and disclosure shall apply during such thirty (30) day period. Any markings, stamps or legends identifying proprietary or confidential information hereunder shall not impose any obligations on another Member inconsistent with this Agreement.

Notwithstanding the foregoing, each receiving Member understands that the disclosing Member and its affiliates are actively engaged in activities, investment, technology exploitation and research and development efforts (collectively, the “Business Activities”), and that Confidential Information disclosed to the receiving Members may include, without limitation, descriptions of ideas, works in progress and projects in development that may be similar to or coincident with such Business Activities. Each Member further acknowledge that such Business Activities may have originated with the disclosing Member’s employees (or those of its affiliates) or others and may duplicate, parallel or resemble portions of the Confidential Information. The Members agree that this Agreement shall in no way limit, restrict or preclude any Member from pursuing any of its present or future Business Activities or interests, either alone or in conjunction with others, or from entering into any agreement or transaction of any kind with any other person, regardless of whether the subject matter of any such agreement or transaction involves elements similar to or coincident with Confidential Information exchanged hereunder or is in any other way similar to or coincident with any transaction considered or evaluated by the Members.

3. The above restrictions on use and disclosure of properly marked Confidential Information shall not apply to such data if the same:

- a. Is in the public domain or in the possession of the receiving Member without restriction at the time of receipt under this Agreement;
- b. Is used or disclosed with prior written approval of the disclosing Member;
- c. Is used or disclosed after ten (10) years from the date of first receipt under this Agreement;
- d. Is developed independently by the receiving Member;
- e. Has been rightfully received by the receiving Member from a third party without breach of this Agreement or other wrongful act of the receiving Member;

f. Is made available by the disclosing Member to a third party, except to the US Government, on an unrestricted, non-confidential basis; and

g. Was known and can be shown by clear and convincing evidence to have been known by the receiving Member at the time of its disclosure by the disclosing Member.

In addition, each Member understands and agrees that all information, ideas, suggestions and concepts of a general nature or commonly known in the industry related to the exploitation of information and entertainment through electronic multimedia and interactive products and services that may be offered in meetings, consultations or documents exchanged between the Members shall not be deemed included in the Confidential Information of any Member, and no Member shall be under any obligation to any other Member with respect to its own use thereof.

In the event a receiving Member is required to disclose a disclosing Member's properly marked Confidential Information pursuant to a final binding order of a governmental agency or court of competent jurisdiction, the receiving Member shall give the disclosing Member reasonable notice of the pendency of such an order. Additionally, in the event that one Member is requested or required to disclose any of the Confidential Information in an investigatory, legal, regulatory or administrative proceeding, such Member will provide the other Members with prompt notice thereof so that such other Members may seek a protective order or other appropriate remedy. However, if no such order or remedy is obtained, such Member may, without liability hereunder, disclose in such proceeding that portion of the Confidential Information that its legal counsel has advised it is legally required to be disclosed.