

BASE AGREEMENT BETWEEN

**Advanced Technology International (ATI)
Consortium Manager (CM) for
The Medical Technology Enterprise Consortium (MTEC)**

**315 Sigma Drive
Summerville, SC 29486**

AND

**Base Agreement Awardee Name
Address**

Concerning

**Support of the Medical Technology Enterprise Consortium (MTEC) Research,
Development, Production, and Commercialization Efforts**

Base Agreement Number:

Authority: MTEC Prototypes Other Transaction Agreement (pOTA) No. W81XWH-15-9-001 and 10 U.S.C. § 2371b, Section 815 of the 2016 National Defense Authorization Act, P.L 114-92, as amended

This Agreement is entered into between Advanced Technology International (ATI), Consortium Manager for the Medical Technology Enterprise Consortium (MTEC), and [Organization Name], "Base Agreement Awardee". This Agreement constitutes the entire understanding and agreement between the parties with respect to the subject matter hereof and supersedes all prior representations and agreements. It shall not be varied except by an instrument in writing of subsequent date duly executed by an authorized representative of each of the parties. The validity, construction, scope and performance of this Agreement shall be governed by the laws of the state of South Carolina, excluding its choice of laws rules.

ADVANCED TECHNOLOGY INTERNATIONAL	[ORGANIZATION NAME]
_____ (Name & Title)	_____ (Name & Title)
_____ (Signature)	_____ (Signature)
_____ (Date)	_____ (Date)

MTEC BASE AGREEMENT

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BASE AGREEMENT

ARTICLE 1. PREAMBLE

- 1.1.** The Government has expressed an interest in collaboration with an industry and academia consortium to conduct research and development in cooperation with the Government leading to technology demonstrations in biomedical sciences and other related fields to maintain and improve Service member health and performance in diverse environments.
- 1.2.** Industry and academia have entered into a Consortium Member Agreement to participate in the Medical Technology Enterprise Consortium (MTEC) for the purpose of conducting research, development, and testing in cooperation with the Government leading to technology demonstrations in the biomedical sciences and other related fields to maintain and improve Service member health and performance in diverse environments. The MTEC has retained the services of Advanced Technology International, as its Consortium Manager (CM) to manage the affairs of the consortium and fulfill MTEC's responsibilities. The Government envisions entering into projects with MTEC Members through its Consortium Manager. The Government and the Consortium intend to conduct individual and collaborative research, development, and testing leading to technology demonstrations that advance the state-of-the-art of technology as needed to develop and transition new materiel technologies and improve medical practice. The scope of this collaborative Research and Development (R&D) effort includes:
 - 1.2.1. Research and prototyping to support US Army Medical Research and Materiel Command (USAMRMC) requirements;
 - 1.2.2. Capitalization of promising, private sector technology opportunities to include investing in small companies that are developing promising technologies, drugs, and biologics;
 - 1.2.3. Providing funding for critical studies that may attract other investors;
 - 1.2.4. Making Government-developed Intellectual Property (IP) and supporting data available to Industry through licensing for exploitation in both commercial and military products;
 - 1.2.5. Procurement and production of military stocks to include additional testing and modification needed to meet military requirements; and
 - 1.2.6. Collaborative efforts with interested parties sharing common goals.
- 1.3.** The purpose of this Agreement is to provide a vehicle to conduct research, development, and testing, leading to technology demonstrations that support the objectives set forth in Article 4, Technology Objectives. The Government shall provide the information necessary for the MTEC Consortium Manager to issue Requests for Project Proposals. Notice of these Requests for Project Proposals may be advertised to industry via FEDBIZOPPS. The CM shall make Requests for Project Proposals available to MTEC

Members. MTEC Members will then decide whether to submit a Research Project Proposal in response and, if so, will prepare their individual proposal(s). These MTEC Member proposals will be submitted to the MTEC CM. The CM will review the proposals for completeness and conformity with format requirements laid out in the Request for Project Proposals and transmit all proposals to the Government. The CM will conduct an evaluation of the cost proposal submitted by the MTEC member, and provide a summary of the cost reasonableness determination to the Government to be used in the Government's determination in making the award. The CM will maintain a website capable of sharing pre-award documentation with the government. Documentation includes but is not limited to pre-announcements, Requests for Project Proposal, proposals, whitepapers, and proposal evaluations. The Government shall be responsible for evaluation and selection of proposals for project funding from among the proposals submitted. Once it receives notification of selection of a project for funding through a Project Approval Letter (PAL) and funding through a pOTA Task Order, the MTEC CM will enter into a Research Project Award with the MTEC Member entity whose proposal was selected by the Government. The MTEC CM shall execute and administer the Research Project Award, and the Government's designated Sponsor's Office Technical Representative (SOTR) will monitor the technical work performed by the Research Project Awardee.

- 1.4. The essential core capabilities of the Consortium include research and prototyping, capitalization of private sector technology opportunities, technology transfer, and commercialization of Government IP, including follow-on production as authorized under 10 USC 2371.
- 1.5. In consideration of the foregoing, the MTEC CM and Base Agreement Awardee agree to the mutual covenants and promises contained in this Agreement.

ARTICLE 2. DEFINITIONS

- 2.1 When used in this Agreement, the following terms, whether used in the singular or plural, shall have the meanings set forth herein.
- 2.2 "Agreement" or "Base Agreement" means the agreement between the MTEC CM and the MTEC member organization that serves as the baseline agreement for all future funded Research Project Awards. .
- 2.3 "Agreements Officer" (AO) means the person identified by the Government in the MTEC pOTA authorized to obligate the Government for any Research Project Award issued hereunder.
- 2.4 "Agreements Officer Representative" (AOR) means the person designated by US Army Medical Research Acquisition Activity (USAMRAA) to be responsible for managing the scientific and technical aspects of the MTEC pOTA and assisting with agreement administration.
- 2.5 "Agreements Specialist" means the person identified by the Government to assist the Agreements Officer.

- 2.6** “Base Agreement” means the agreement between the MTEC CM and the MTEC member organization that serves as the baseline agreement for all future funded Research Project Awards. The Base Agreement flows down applicable terms and conditions from this Other Transactions Agreement between the Government and MTEC through its CM.
- 2.7** “Cash Contribution” means the Consortium and/or the Research Project Awardee (or Awardees’ lower tier subawards) financial resources expended to perform a Research Project. The cash contribution may be derived from the Consortium’s or Research Project Awardee (or Awardees’ subawards) funds or outside sources or from nonfederal contract or grant revenues or from profit or fee on a federal procurement contract. A Member’s own source of funds may include corporate retained earnings, current or prospective Independent Research and Development (IR&D) funds or any other indirect cost pool allocation. New or concurrent IR&D funds may be utilized as a cash contribution provided those funds identified by the Consortium Members will be spent on performance of the Statement of Work (SOW) of a Research Project or specific tasks identified within the SOW of a Research Project. Prior IR&D funds will not be considered as part of the Consortium Member’s cash or In Kind contributions, except when using the same procedures as those that authorize Pre-Award Costs, nor will fees be considered on a Consortium Member’s cost sharing portion. Cash contributions include the funds a Consortium Member will spend for labor (including benefits and direct overhead), materials, new equipment (prorated if appropriate), awardees’ subaward efforts expended on the SOW of a Research Project, and restocking the parts and material consumed.
- 2.8** “Consortium” means the Medical Technology Enterprise Consortium (MTEC), a non-stock corporation, whose Members represent industry, academia, for profit organizations, non-profit organizations, not-for-profit organizations, and other entities, such as consortia, foundations and alliances.
- 2.9** “Consortium Manager” (CM) means the organization delegated authority by the MTEC to execute and administer the efforts under the MTEC Other Transactions Agreement as defined in the specific agreement entered into between the MTEC and the CM.
- 2.10** “Consortium Member” or “Consortium Members” means the individual organizations that are Members of the MTEC and signatories to the Consortium Member Agreement.
- 2.11** “Consortium Member Agreement” (CMA) means the Agreement governing the rights and obligations of the Consortium Members as they relate to the Consortium and each other.
- 2.12** “Cure Notice” means written notification provided to the Parties concerning the terms and or conditions of this Agreement or a Research Project Award not being met prior to the Government taking action, as set forth in Article 13.
- 2.13** “Effective Date” means the date on which this Agreement is signed and executed.
- 2.14** “Field” means the field of biomedical sciences and related fields as applied to the maintenance and improvement of Service member health and performance in diverse environments.

- 2.15** “Government” means the United States of America represented by the USAMRMC and USAMRAA.
- 2.16** “Government Fiscal Year” (FY) means the period commencing on October 1 and ending September 30 of the following calendar year.
- 2.17** “Independent Research and Development (IR&D)” means a Consortium Member’s cost relative to projects falling within the four following areas: (a) basic research, (b) applied research, (c) development, and (d) system and other concept formulation studies. The term does not include the cost of effort sponsored by a grant or required in the performance of a contract. IR&D effort shall not include technical effort expended in developing and preparing technical data specifically to support submitting a bid and proposal.
- 2.18** “In Kind Contribution” means the Consortium Members' non-financial resources expended by the Consortium Members to perform a Research Project such as wear-and-tear on in-place capital assets like machinery or the prorated value of space used for performance of the Research Project, and the reasonable fair market value (appropriately prorated) of equipment, materials, IP, and other property used in the performance of the SOW of the Research Project.
- 2.19** “Nonprofit Research Institution” means an entity whose primary purpose is conducting research and that is (1) described in section 501(c) of the IRS code of 1986, AND (2) exempt from tax under section 501(a) of that code
- 2.20** “Nontraditional Defense Contractor” means an entity that is not currently performing and has not performed, for at least the one-year period preceding the solicitation of sources by the Department of Defense for the procurement or transaction, any contract or subaward for the Department of Defense that is subject to full coverage under the cost accounting standards prescribed pursuant to section 1502 of title 41 and the regulations implementing such section.
- 2.21** “Parties” means, unless otherwise defined in a specific Article, the CM and the Base Agreement Awardee where collectively identified, and “Party” where each entity is individually identified.
- 2.22** “Prototype Other Transactions Agreement” (pOTA) means this Other Transactions Agreement entered into by the MTEC CM and the Government.
- 2.23** “Project Approval Letter” (PAL) means the Research Project Awardee selection decision and authorizes the CM to award a Research Project Award. A PAL will include approved Statement of Work, award value, current funding, specific key Research Project considerations, and designated SOTR. The PAL may be used for a modification to an existing Research Project Award.
- 2.24** “Pre-Award Costs” are those costs that directly support the SOW approved by the AO that must be incurred before the signing of the Research Project Award in order to meet the agreed to schedule. Documentation for Pre-award Costs must be provided in a written request by the Research Project Awardee through the CM and approved in writing by the AO prior to the costs being incurred.

- 2.25** “Research Plan” means the research and development areas identified by the Government through technology objectives to meet new and emerging technical needs for military biomedical science.
- 2.26** “Research Project Proposal” means a proposal from the MTEC Member submitted through the CM to the Government for consideration for a Research Project Award.
- 2.27** “Request for Project Proposal” means the Government’s request for proposals issued by the CM to MTEC members, based on the Technology Objectives or other mission requirements determined by the Government. Such request will include the technical, management, and cost factors as appropriate that will be used as the Government’s basis for award selection.
- 2.28** “Research Project Awardee” means the MTEC member that is issued a Research Project Award by MTEC through its CM.
- 2.29** “Research Project Award” means an agreement between MTEC through its CM, and the MTEC member entity whose proposal is evaluated and selected by the Government for funding, establishing the scope of work, terms and conditions for the MTEC member entity’s performance and payment under the Government funded project. These awards may be of any type to include, but not limited to, firm fixed price, cost plus fixed fee, cost reimbursement, and cost share.
- 2.30** “Research Project Proposals” means proposals submitted by MTEC Members that are in response to a Request for Project Proposal.
- 2.31** Sponsor’s Office Technical Representative (SOTR) means the individual designated by the Government on a per-project basis to monitor all technical aspects and assist in agreement administration of a Research Project Award.
- 2.32** “Subawardee” means any supplier, distributor, vendor, or firm that furnishes supplies or services to or for a Research Project Award.
- 2.33** “Subject Invention” means any Invention Made in the performance of work under this Agreement. Such Inventions may be Made by employees or contractors or others working on behalf of the Project Agreement Awardee, the Government, or any combination thereof. "Invention" and "Made" have the meanings set forth in Title 15 U.S.C. Section 3703(7) and (8).
- 2.34** “Task Order” or “pOTA Task Order” means an award issued under the pOTA from the Government to the MTEC CM which provides funding and scope for Research Project Awards.
- 2.35** “Technology Objectives” mean broad research areas identified by the Government.
- 2.36** “USAMRMC” means the U.S. Army Medical Research and Materiel Command.
- 2.37** “U.S. Army Medical Research Acquisition Activity” or “USAMRAA” is the contracting organization in USAMRMC. USAMRAA is the authorized representative of the Department of the Army to contract and administer the pOTA.

ARTICLE 3. RESPONSIBILITIES

- 3.1 Government Responsibilities.** The Government will provide updated Technology Objectives, periodic briefings, and ongoing guidance for Research Project Proposals.

3.1.1. The Government may:

- 3.1.1.1. Provide strategic and/or technical guidance
- 3.1.1.2. Directly participate in the work to be performed under the Research Project Awards
- 3.1.1.3. Provide full or partial funding
- 3.1.1.4. Share expertise and facilities
- 3.1.1.5. Participate as the Government Sponsor with MTEC arranged meetings including membership/ recruiting events, program reviews, audio/video tele-conferences, and other industry related events.

3.1.2. The Government shall:

- 3.1.2.1. Retain technically acceptable, unfunded proposals for two years for potential funding at a future time
- 3.1.2.2. Issue requests for Request for Project Proposals through the CM
- 3.1.2.3. Evaluate MTEC Member Research Project Proposals and make Research Project Award decisions
- 3.1.2.4. Provide technical oversight of Research Project Awards
- 3.1.2.5. Assess efficiency and effectiveness of Consortium Management activities.

3.2 Consortium Responsibilities. The Consortium's primary purpose is to provide cutting edge knowledge, materiel technologies, and effective materiel life cycle management to protect, treat, and optimize Warfighters' health and performance across the full spectrum of military operations. To achieve that purpose, the Consortium shall:

- 3.2.1. Receive requirements, funding, and Research Project Awards from USAMRMC;
- 3.2.2. Be dedicated to fulfilling these requirements by providing cutting edge, innovative solutions at the lowest initial and life cycle cost;
- 3.2.3. Provide effective program/project integration and planning leading to U.S. Food and Drug Administration (FDA) licensure and to commercialization when feasible;
- 3.2.4. Effectively market the MTEC through social media and other platforms to obtain private funding in support of prototype development, shared interests, and MTEC growth and sustainability. Continually seek out and enroll members that enhance the military medical technology and industrial bases; and

- 3.2.5. Promote teaming and technology transfer to achieve optimal performance.
- 3.3 Consortium Members' Responsibilities.** Consortium Members may submit Research Project Proposals in response to a solicitation. The Consortium Member may provide partial funding, either as Cash Contributions or In Kind Contributions or a combination of Cash and In Kind. Research Project Awardees shall be responsible to the Consortium and the Government for performing their obligations under the Research Project Award and their Base Agreement.
- 3.4 Consortium Manager Responsibilities.** The MTEC delegates responsibility to the Consortium Manager for the overall day-to-day administration of the pOTA, including, but not limited to, MTEC's technical, programmatic, reporting, financial, administrative and contractual obligations under the pOTA and resulting Research Project Awards. Specifically, the CM shall:
- 3.4.1 Assist Government in development of Requests for Project Proposals
 - 3.4.2 Coordinating co-funding opportunities on specific government planned solicitations
 - 3.4.3 Provide Requests for Project Proposals to MTEC members
 - 3.4.4 Receive and screen MTEC member Research Project Proposals
 - 3.4.5 Perform evaluation of the cost proposal submitted by the MTEC member and provide a cost analysis summary to the Government Agreements Officer for consideration in the Government's award determination.
 - 3.4.6 Negotiate and award Base Agreements and Research Project Awards with MTEC members whose Research Project Proposals have been selected by the Government for award.
 - 3.4.7 Participate, as required, with the Government in the planning, programming and budgeting of the project.
 - 3.4.8 Administer Research Projects Awards under Base Agreements.
 - 3.4.9 Provide summary business and technical reports based on input from Research Project Awardees.
 - 3.4.10 Perform close-out of Research Project Awards.
- 3.5 Additional Government Participation.** Other Services, Defense Advanced Research Projects Agency, Defense Threat Reduction Agency, Health and Human Services and other organizations within the U. S. Government may participate in the collaborative activities of the MTEC pOTA to the extent permitted by applicable laws and regulations.

ARTICLE 4. TECHNOLOGY OBJECTIVES

- 4.1. General.** The Consortium will support the Government in attaining Technology Objectives (TOs), which are specific to Command requirements to develop biomedical products and procedures to protect, project, and sustain the force. Technology Objectives include the following:
- 4.1.1. **Prevention, Diagnosis, and Treatment of Military Infectious Disease.** This TO focuses on infectious diseases encountered by Service members during deployment and those that can significantly impact performance. Research and development efforts may include vaccines, anti-parasitic drugs, deployable field clinical diagnostics (human and vector), prophylactics and novel therapeutics to treat multi-drug resistant organisms in combat wound infections, and vector control - pertinent to naturally occurring endemic diseases with demonstrated or potential capability to decrease military operational effectiveness.
 - 4.1.2. **Care of Combat Casualties.** This TO focuses on the development of medical interventions that can be used on the battlefield to reduce morbidity and mortality. Research and development may include efforts to develop and evaluate drugs, biologics, and/or devices for hemorrhage control, resuscitation and blood products; diagnosis and treatment of traumatic brain injury and spinal cord injury; treatments for extremity trauma, tissue injury, lung injury and burns; en-route care and intensive critical care (including advanced monitoring and pre-hospital care).
 - 4.1.3. **Support for Military Operational Medicine.** This TO focuses on developing effective countermeasures against stressors and to maximize health, performance, and fitness. Research and development efforts may include diagnostics, treatments, and training solutions to prevent or reduce injury and improve physiological and psychological health and resilience. This TO also includes environmental health and protection including the assessment and sustainment of health and the operational effectiveness of Service members exposed to harsh operational environments including altitude, cold, heat, and exposure to environmental health hazards.
 - 4.1.4. **Support for Clinical and Rehabilitative Medicine.** This TO focuses on innovation in definitive and rehabilitative care to reset wounded Service members in terms of duty, performance, and quality of life. Efforts may include developing medical technologies (drugs, biologics, and/or devices) and treatments/rehabilitation strategies (methods, guidelines, standards, and information) for acute and chronic pain management, regenerative medicine and composite tissue engineering, neuromusculoskeletal injuries (including advanced prosthetics and orthotics), and the restoration of vision, hearing, and/or balance following traumatic injury.
 - 4.1.5. **Support for Medical Training and Health Information Science.** This TO focuses on exploring the implications for the use of technology for medical training and for the provision, management, and support of health services in the military. Research and development efforts may include improving military medical training through

medical simulation, educational gaming, and objective training metrics, and improving the use and sharing of health related data for better strategic planning, process development, and software applications.

4.1.6. Prevention, Diagnosis, and Treatment of Disease and Injury from Chemical and Biological Agents and Radiation. This TO focuses on developing effective medical prophylaxes and treatments to sustain force effectiveness in a chemical, biological, or radiological environment. Efforts may include development of drugs, biologics, vaccines, and diagnostic tests and tools.

4.2. Revision of Technology Objectives. The TOs will be provided to the MTEC and the MTEC CM shall post the TOs on its website for MTEC members. The Government may revise the TOs at any time and will provide the MTEC any such updates which will be posted on the MTEC website for members.

4.3. Purpose of Technology Objectives. Request for Project Proposals will be guided by the Technology Objectives

ARTICLE 5. REPORTS

5.1. Research Project Awardees shall maintain records of the research and development activities performed and funds expended under the Research Project Awards. All the records shall include the results of studies, analyses, tests and other investigations conducted as part of the Research Project Award.

5.2. The Research Project Awardees shall submit additional documentation as prescribed by individual Research Project Awards. The documentation described below is the minimum reporting requirements in each award:

5.2.1. Quarterly and Annual Reports

5.2.1.1. Technical Status Report. Quarterly and annually (if effort is for more than one year). The technical status report shall detail technical progress to date and report on all problems, technical issues or major developments during the reporting period. The CM may specify additional reporting requirements.

5.2.1.2. Business Status Report. The business status report shall provide summarized details of the resource status of all Research Project Awards awarded under this Base Agreement. This report will include a quarterly accounting of current expenditures. Any major deviations from the agreed to project plan shall be explained with a discussion of proposed actions to address the deviations.

Quarterly Reports shall be submitted to mtec-deliverables@ati.org by the 25th calendar day following prior calendar quarter close based on the following schedule:

Report Months	Due Date
January – March	25 April
April - June	25 July
July - September	25 October
October - December	25 January

5.2.2. General Report Requirements.

5.2.2.1. Technical reports will provide a concise and factual discussion of the significant accomplishments and progress made during the reporting period. Each of the topics described below shall be addressed for the effort performed:

- A comparison of actual accomplishments with the goals and objectives established for the period;
- Reasons why established goals and objectives were not met, if appropriate;
- Other pertinent information including, and when appropriate, analysis and explanation of cost variances;
- A cumulative chronological list of written publications in technical journals, papers, or other presentations at meetings, conferences, seminars, etc. regarding the Research Project. All reports will identify resubmissions to publications, information, and/or notification of status of publication submissions; and
- New discoveries, inventions, or patent disclosures, and specific applications stemming from the Research Project effort provided that such disclosures shall not compromise IP rights of the Government, Consortium, or Consortium Members.

5.2.2.2. Business Status Reports. See Section 5.2.1.2.

5.2.2.3. Final Technical Report (FTR)

- A Draft FTR shall be submitted to the SOTR and the MTEC CM within sixty (60) calendar days of the completion of the work under a Research Project Award. This report will provide a comprehensive cumulative and substantive summary of the progress and significant accomplishments achieved during the total period of the Research Project effort. Each of the topics described above shall be addressed as appropriate for the effort performed. The SOTR shall provide written comments on the Draft FTR to the Research Project

Awardee within thirty (30) calendar days of receipt of the report. The FTR shall be submitted within fourteen (14) calendar days of receipt of the SOTR comments on the Draft FTR. If the FTR is acceptable, as submitted, the SOTR will forward his/her approval within thirty (30) calendar days to the CM.

- Format. The cover and title page shall be Standard Form 298, Report Documentation Page. Item 13 of the form should contain a 200 to 300 word abstract summarizing technical progress during the reporting period. Style should be third person singular using past tense. Jargon, special symbols or notations, subscripts, mathematical symbols, or foreign alphabet letters are not permitted. All pages should be prepared for acquisition and distribution by the Defense Technical Information Center (DTIC). All pages should be good quality for copying purposes. The report shall be prepared in accordance with American National Standards Institute (ANSI) document Z39.18-1987, "Scientific and Technical Reports: Organization, Preparation, and Production," which may be obtained from American National Standards Institute, Incorporated, 1430 Broadway, New York, NY 10018.
- Once the SOTR has informed the CM that the FTR has been approved, the Research Project Awardee shall forward a copy of the FTR to the Defense Technical Information Center, ATTN: DTIC-O, 8722 John J. Kingman Road, Suite 0944, Fort Belvoir, VA 22060-6218.
- The FTR front page shall be marked in a conspicuous place with a distribution statement to denote the extent of its availability for distribution, release, and disclosure without additional approvals or authorizations. Unless otherwise instructed, the distribution statement shall follow the instructions available at the following link: https://mrmc.amedd.army.mil/index.cfm?pageid=researcher_resources.technical_reporting.

5.2.2.4. Final Business Status Report

- The final business status report shall summarize details of the resource status of a Research Project Award, including the status of the contributions by all participants. This report will include a final accounting of incurred expenditures.
- A commercial format shall be used for the final report. The report must be submitted within 90 calendar days after the completion of the project.

ARTICLE 6. OBLIGATION AND PAYMENT

- 6.1. Payment Method Types.** Research Project Awards will be issued as either a fixed price milestone payment method or a cost reimbursement milestone payment method as described below.

6.1.1. Fixed Price Milestone Payment Method: Payments shall be made in accordance with the Payable Milestone Schedule of each Research Project Award, provided the designated SOTR has verified compliance with the Statement of Work and accomplishment of the stated effort. The Payable Milestone Schedule may be revised as appropriate and deemed necessary by issuance of a bilateral modification to the Research Project Award. Quarterly reviews by the SOTR and the CM will assess the need for revisions to the Payable Milestone Schedule. An acceptable invoice for adjustable fixed price milestone payments is one that (on the invoice or on the Payable Milestone Report):

6.1.1.1. contains the date of invoice and the Base Agreement number and Research Project Award number;

6.1.1.2. identifies any associated technical milestones and the progress toward completion of each milestone; and

6.1.1.3. lists the milestone cost negotiated and contained in each Research Project Award

6.1.2. Cost Reimbursable Milestone Payment Method (with not to exceed ceiling): Payment is contingent upon satisfactory progress toward completion of milestones as delineated in Research Project Award. Payment shall be made based on actual costs incurred in completing milestones up to the maximum amount allowable under the applicable Research Project Award, provided the designated SOTR has verified compliance with the Statement of Work and accomplishment of the stated effort. Either a Status Report identifying any associated technical tasks and the progress toward completion of each milestone, a Deliverable Report, or a Milestone Report is required concurrent with the invoice. An acceptable invoice for reimbursable payment is one that (on the invoice or on the attached Status, Deliverable, or Milestone Report in accordance with each Research Project Award):

6.1.2.1. contains the date of invoice and the Base Agreement number and Research Project Award number;

6.1.2.2. identifies any associated technical milestones and the progress toward completion of each milestone;

6.1.2.3. includes a description of supplies and services, labor costs, subcontractor costs, material costs, travel costs, other direct costs, indirect costs, and extended totals;

6.1.2.4. indicates the current period and cumulative man-hours and costs incurred through the period indicated on the invoice; and

6.1.2.5. contains the following certification statement:

"I certify that the amounts invoiced are for costs incurred in accordance with the agreement, the work reflected has been performed, and prior payment has not been received."

Authorized Signature _____

6.1.3. Cost Plus Fixed Fee Milestone Payment Method (with not to exceed ceiling):

Payment is contingent upon satisfactory progress toward completion of milestones as delineated in Research Project Award. Payment shall be made based on actual costs incurred in completing milestones up to the maximum amount allowable under the applicable Research Project Award, provided the designated SOTR has verified compliance with the Statement of Work and accomplishment of the stated effort. The Project Agreement Awardee will normally fund any costs incurred above this maximum amount. Either a Status Report identifying any associated technical tasks and the progress toward completion of each milestone, a Deliverable Report, or a Milestone Report is required concurrent with the invoice. Payment of the fixed fee specified in each Research Project Award, subject to any adjustments required by other provisions of this Base Agreement and/or Research Project Award, will be paid in installments at the time of each provisional payment on account of the allowable costs. The amount of fixed fee paid will be based upon the ratio that the Research Project Awardee's incurred allowable costs bear to the total estimated cost. In the event the work cannot be completed within the estimated cost, the CM may increase the estimated cost without increasing the fixed fee.

An acceptable invoice for reimbursable payment is one that (on the invoice or on the attached Status, Deliverable, or Milestone Report in accordance with each Research Project Award):

- 6.1.3.1. contains the date of invoice and the Base Agreement number and Research Project Award number;
- 6.1.3.2. identifies any associated technical milestones and the progress toward completion of each milestone;
- 6.1.3.3. includes a description of supplies and services, labor costs, subcontractor costs, material costs, travel costs, other direct costs, indirect costs, fixed fee and extended totals;
- 6.1.3.4. indicates the current period and cumulative man-hours and costs incurred through the period indicated on the invoice; and
- 6.1.3.5. contains the following certification statement:

"I certify that the amounts invoiced are for costs incurred in accordance with the agreement, the work reflected has been performed, and prior payment has not been received."

Authorized Signature _____

6.1.4. Cost Reimbursable, Cost Sharing Milestone Payment Method (with not to exceed ceiling): Payment is contingent upon satisfactory progress toward completion of milestones as delineated in Research Project Award and acceptable cost share. Payment shall be made based on actual costs incurred in completing milestones up to the maximum amount allowable under the applicable Research Project Award, provided the designated AOR has verified compliance with the Statement of Work and accomplishment of the stated effort. Either a Status Report identifying any associated technical tasks and the progress toward completion of each milestone, a Deliverable Report, or a Milestone Report is required concurrent with the invoice. An acceptable invoice for reimbursable payment is one that (on the invoice or on the attached Status, Deliverable, or Milestone Report in accordance with each Research Project Award):

- 6.1.4.1. contains the date of invoice and the Base Agreement number and Research Project Award number;
- 6.1.4.2. identifies any associated technical milestones and the progress toward completion of each milestone;
- 6.1.4.3. includes a report of the cost share expended towards the accomplishment of the SOW tasks and/or milestones. This cost share report may be attached to the invoice if contractor practices make inclusion of such information on the invoice itself impractical. If the cost share report is separate from the invoice, it must be signed by an authorized representative. This cost share report must contain a breakout of the cost share by cost element similar to the level of detail required on the invoice and any in-kind contributions. The preferred method of reporting cost share is to provide an invoice for actual cost incurred with a value for the cost shared amount and the value to be reimbursed by the Government through the CM;
- 6.1.4.4. includes a description of supplies and services, labor costs, subcontractor costs, material costs, travel costs, other direct costs, indirect costs, and extended totals;
- 6.1.4.5. indicates the current period and cumulative man-hours and costs incurred through the period indicated on the invoice; and
- 6.1.4.6. contains the following certification statement:

"I certify that the amounts invoiced are for costs incurred in accordance with the agreement, the work reflected has been performed, and prior payment has not been received."

Authorized Signature _____

6.2. Submission of Invoices

- 6.2.1. Invoices may be submitted no more frequently than monthly. The Research Project Awardee shall submit invoices and any necessary supporting documentation to 'Advanced Technology International' via email at mtec-ap@ati.org.
- 6.2.2. Research Project Awardee's final invoice (completion invoice) will be clearly indicated as such and shall indicate the cumulative amounts incurred and billed to completion, and a written certification of the total hours expended. Actual project costs incurred and cost share performance, if applicable, of each project shall be reported and reviewed each quarter.

6.3. Payment Terms

- 6.3.1. Payment terms are NET 30 days after CM's receipt of an acceptable invoice. An acceptable invoice is one that meets the conditions described in this Article.

6.4. Limitation of Funds: CM's financial liability will not exceed the amount made available by the Government to CM and obligated by CM under the Research Project Award for Research Project Awardee's projects under the pOTA.

6.5. Statement of Requirements. The Base Agreement Awardee shall provide the necessary personnel and facilities to perform the applicable work requirements and shall furnish the supplies/services outlined in each Research Project Award in accordance with the terms and conditions set forth in this Base Agreement and any additional terms included in each Research Project Award.

It is understood and agreed that CM has no obligation under the terms of this Base Agreement to issue any Research Project Awards.

ARTICLE 7. ADMINISTRATION

7.1. Financial Records and Audit Access. The costs incurred under any Research Project Award shall be those costs that are reasonable and prudent. Actual costs, including those direct costs associated with the research project as well as any indirect costs are reimbursable to the extent they have a significant relationship to providing the goods or service under the research project award. The AO or authorized

representative shall have direct access to sufficient financial records to ensure full accountability for all government funding or statutorily required cost share under any Research Project Award for a period of three (3) years after final payment, unless notified otherwise by the Agreements Officer. The Agreements Officer or authorized representative, shall have the right to examine or audit the Research Project Awardee, or subaward records during the period of the agreement and for three (3) years after final payment, unless otherwise notified by the CM. These records are also subject to examination or audit by the Government’s General Accountability Office (GAO). Such audit, examination, or access shall be performed during business hours on business days upon prior written notice and shall be subject to the security requirements of the audited Party. The Research Project Awardee shall provide a statement to the CM when a business unit meets the conditions for use of an Independent Public Accountant (other than pursuant to the Single Audit Act) for any needed audits. The statement shall include the business unit's name, address, expected value of its award, and state the business unit is not currently performing on a procurement contract subject to the Cost Principles (48 CFR Part 31) and/or Cost Accounting Standards (48 CFR Part 99) and refuses to accept Government access to its records.

7.1.1. **Accounting System.** The Research Project Awardees shall have and maintain established accounting systems, which comply with Generally Accepted Accounting Principles and shall ensure that appropriate arrangements have been made for receiving, distributing, and accounting for Federal funds. An adequate accounting system is normally accomplished through a job order cost accounting system, whereby the books and records segregate direct costs by agreement/contract, and includes an established allocation method for the equitable allocation of indirect costs among agreements/contracts.

7.1.2. **Comptroller General Access to Records.** The Comptroller General shall have access to records for prototype projects that provide for total payments in excess of \$5,000,000.

7.2. Administrative Responsibilities. The following administrative provisions apply to this Base Agreement and, tailored as appropriate, will be included in all Research Project Awards pursuant to this Agreement:

7.2.1. **Administrative Matters.** Administrative matters under this Agreement and the Research Project Awards pursuant to this Agreement shall be referred to the following representative:

Base Agreement Awardee	Consortium Manager
Organization Name	Advanced Technology International
Address	315 Sigma Drive

Title: Name: Telephone: E-mail:	Summerville, SC 29483 Contracts Administrator: Rebecca Harmon Telephone: 843-760-3358 E-mail: mtec-contracts@ati.org
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7.3. Technical Matters.

Technical matters under this Agreement shall be referred to the following representative:

Base Agreement Awardee	MTEC Consortium Manager
Organization Name Address Title: Name: Telephone: E-mail:	Advanced Technology International 315 Sigma Drive Summerville, SC 29483 Kathy Zolman Telephone: 843-760-4349 E-mail: kathy.zolman@ati.org

**A Sponsor’s Office Technical Representative (SOTR) will be identified on each Research Project Award.

7.4. Management of Research Project Awards. Performance of the work on Research Project Awards is subject to the technical direction of the SOTR designated in the Research Project Award.

7.4.1. For the purposes of this clause, technical direction includes the following:

7.4.1.1. Direction to the Research Project Awardee, which shifts work emphasis between work areas or tasks, requires pursuit of certain lines of inquiry, fills in details or otherwise serves to accomplish the objectives described in the statement of work;

7.4.1.2. Guidelines to the Research Project Awardee that assist in the interpretation of drawings, specifications or technical portions of work description.

7.4.1.3. Review and, where required by the Research Project Award, approval of technical reports, drawings, specifications, or technical information to be delivered by the Research Project Awardee under the Research Project Award.

7.4.2. The SOTR shall monitor the Research Project Awardee's performance with respect to compliance with the technical requirements of the Research Project Award.

7.4.3. Technical direction must be within the general scope of work stated in the Research Project Award. Technical direction may not be used to:

7.4.3.1. Assign additional work under the Research Project Award;

7.4.3.2. Increase or decrease the estimated Research Project Award cost, fee (if any), or the time required for the research and development period of performance;

7.4.3.3. Change any of the terms, conditions or specifications of the Research Project Award; or

7.4.3.4. Accept non-conforming work.

7.4.4. As such, no verbal or written request, notice, authorization, direction or order received by the Research Project Awardee shall be binding upon the MTEC, CM or Government, or serve as the basis for a change in the Research Project Award cost or any other provision of the Research Project Award, unless issued (or confirmed) in writing by the MTEC CM Contractual Representative designated in the Research Project Award.

7.4.5. The Research Project Awardee shall immediately notify the CM Contractual Representative whenever a verbal or written change notification has been received from anyone other than the CM Contractual Representative, which would affect any of the terms, conditions, cost, schedules, etc. of the Research Project Award, and the Research Project Awardee is to perform no work or make any changes in response to any such notification or make any claim on the Consortium through its CM or Government, unless the CM Contractual Representative directs the Research Project Awardee, in writing, to implement such change notification.

7.5. Modifications. The only method by which this Base Agreement or a Research Project Award may be modified is by a formal, written modification signed by the CM Contractual Representative.

7.5.1. **Bilateral Modifications.** The CM or Base Agreement Awardee may propose modifications to this Agreement. A modification that materially changes the obligations of either Party must be in writing and signed by the Research Project Awardee and an authorized officer of the CM. Consortium Members may propose modifications to any Research Project Award under which the Member has a Research Project Award, including justifications to support any proposed changes, by submitting a written request through the CM to the Government. The

modification request shall detail the technical, chronological, and financial impact of the proposed change on the Research Project Award.

7.5.2. **Unilateral Modifications.** The CM Contractual Representative may unilaterally issue minor or administrative modifications, which do not materially change the obligations of the Consortium or Consortium Member, such as changes in the paying office or changes to Government personnel identified in the Agreement or Research Project Award. Unilateral modifications will be signed by only the CM Contractual Representative.

7.5.3. **Modification Communications.** No other communications, whether oral or in writing, that purport to change this Agreement or a Research Project Award are valid.

7.6. Pre-Award Costs. Pre-Award costs supporting a Research Project Award may be recognized as acceptable costs only after receiving written AO approval for the costs and only if they are determined to be reasonable, allocable, and allowable. To obtain approval of Pre-Award Costs, Consortium Members must submit their request in writing to the MTEC CM. Each request must contain the costs that the Research Project Awardee intends to incur prior to execution of the Research Project Award, why the effort must be started before award and sufficient cost detail for technical and cost review.

7.7. Subaward Approval. Subawards that are proposed and agreed to during negotiations for a Research Project Award are considered as having CM approval. Modifications to approved Subawards and/or new Subawards, under a Research Project Award, that will significantly impact the teaming arrangement and/or technical approach proposed and accepted require CM approval prior to being executed.

7.8. Incremental Funding. The Government's share for full performance of the Research Project Award(s) shall be determined at time of each award. In no event is the CM obligated to reimburse the Research Project Awardee for expenditures in excess of the total funds allotted by the Government under a Research Project Award, regardless of anything to the contrary in any Termination clause herein or in any Research Project Award. The CM anticipates that from time to time additional amounts will be allotted to Research Project Awards by unilateral modification, until the total Government's share for full performance under the Research Project Award is fully funded.

To minimize interruption of effort due to lack of funds, the Research Project Awardee shall notify the CM Contractual Representative in writing (electronic format acceptable) whenever the amount of funds expended under a Research Project Award, when added to anticipated costs in the next 60 calendar days, will exceed 75% of the amount allotted under the Research Project Award by the Government plus the

Research Project Awardee's corresponding share (if the Research Project Award is a cost-sharing agreement). The Research Project Awardee is not obligated to continue performance or otherwise incur costs in excess of (1) for Fixed Price Research Project Awardees the amount unfunded milestones or portions thereof, or (2) for cost reimbursement and cost plus fixed fee Research Project Awards the amount then allotted to the Research Project Award or, (3) if the Research Project Award is a cost-sharing agreement, the Research Project Awardee's corresponding share, until the AO notifies the CM in writing and the CM notifies the Research Project Awardee recipient in writing, that the amount allotted by the Government has been increased and specifies an increased amount, which shall then constitute the total amount allotted by the Government. When and to the extent that the amount allotted by the Government to this Research Project Award is increased, any costs the Research Project Awardee incurs before the increase that are in excess of (1) the amount previously allotted by the Government or, (2) if this is a cost-sharing agreement, the amount previously allotted by the Government to the Research Project Awardee's corresponding share, shall be allowable to the extent they would have been allowable if incurred afterward, unless the AO directs that the increase is solely to cover specific expenses.

7.9. Using Technical Information Resources. To the extent practical, Research Project Awardees will use the technical information resources of the Defense Technical Information Center (DTIC) and other Government or private facilities to investigate for recent and on-going research and avoid needless duplication of scientific and engineering effort.

7.10. Title and Disposition of Property. In this paragraph, "property" means any tangible personal property other than consumable property, which is actually consumed during the execution of effort under a Research Project Award. The Research Project Awardee must obtain approval from the CM and the AO prior to purchasing property using Government funds. Property listed in a Research Project Proposal that results in a Research Project Award is considered as having received AO approval.

7.10.1. Title to Property. Except as provided in this paragraph, title to property shall vest in the Consortium, Consortium Manager, or the Research Project Awardee upon acquisition. For those items of real property or nonexpendable personal property having a unit acquisition cost of \$10,000 or more, which will be acquired with Government funds, the Government reserves the right to transfer the title to the Federal Government or to a third party named by the Government. If a Research Project Award includes the use of real property or equipment that is purchased with non-federal funds or that is donated by a third party to meet a portion of any required cost sharing or matching, the Government will have a financial interest in the property equal to the Federal participation in the project and such property shall be subject to this Article.

7.10.2. Disposition of Property. At the completion of the Research Project Award, items of property with an acquisition value greater than \$10,000 shall be disposed of in the following manner:

7.10.2.1. Purchased by the Research Project Awardee at an agreed-upon price, the price to represent fair market value, with the proceeds of the sale being returned to the Government. For Research Project Awards with Cost Share, the Research Project Awardee may elect to retain title, without further obligation to the Government, by compensating the Government for that percentage of the current fair market value of the real property or equipment that is attributable to the Federal participation in the project; or,

7.10.2.2. Transferred to a Government research facility with title and ownership being transferred to the Government or to an eligible third party. For Research Project Awards with Cost Share, the Research Project Awardee shall be entitled to compensation for its attributable percentage of the current fair market value of the real property or equipment, plus any reasonable shipping; or

7.10.2.3. Any other Government-approved disposition procedures. The Government shall provide disposition procedures within 120 days of being requested by the CM to provide disposition. The Government is liable for storage costs of any property in storage awaiting disposition after this 120 day period.

7.11. Flow down. The Base Agreement Awardee shall include this Article, suitably modified to identify all parties, in all subawards. This Article shall, in turn, be included in all sub-tier subawards or other forms of lower tier agreements, regardless of tier. The government will be a third party in interest for purposes of this Article in any agreement where flow-down of rights and obligations is required.

ARTICLE 8. PROPRIETARY INFORMATION

8.1. Definitions for Article 8.

8.1.1. "Disclosing Party" means the Consortium, the CM, a Research Project Awardee, or the Government which discloses Confidential Information as contemplated by the subsequent paragraphs.

8.1.2. "Receiving Party" means the Consortium, the CM, a Research Project Awardee, or the Government which receives Confidential Information disclosed by a Disclosing Party.

8.1.3. "Proprietary Information" means information and materials of a Disclosing Party which are designated as Proprietary Information or as a Trade Secret or subject to

export control in writing by such Disclosing Party, whether by letter or by use of an appropriate stamp or legend, prior to or at the same time any such information or materials are disclosed by such Disclosing Party to the Receiving Party. Notwithstanding the foregoing, materials and other information that are orally, visually, or electronically disclosed by a Disclosing Party, or are disclosed in writing without an appropriate letter, stamp, or legend, shall constitute Proprietary Information or a Trade Secret or be subject to export control if such Disclosing Party, within thirty (30) calendar days after such disclosure, delivers to the Receiving Party a written document or documents describing the material or information and indicating that it is proprietary or a Trade Secret or subject to export control. Any disclosure of information by the Receiving Party prior to receipt of such notice shall not constitute a breach by the Receiving Party of its obligations under this Article.

8.1.4. "Trade Secret" means all forms and types of financial, business, scientific, technical, economic, or engineering information, including patterns, plans, compilations, program devices, formulas, designs, prototypes, methods, techniques, processes, procedures, programs, or codes, whether tangible or intangible, and whether or how stored, compiled, or memorialized physically, electronically, graphically, photographically, or in writing if,

8.1.4.1. The owner thereof has taken reasonable measures to keep such information secret; and

8.1.4.2. The information derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable through proper means by, the public.

8.2. Exchange of Information. The Government may from time to time disclose Government Proprietary Information to the Consortium, the CM, a Research Project Awardee in connection with the Research Projects and the Consortium, a Consortium Member or Members may from time to time disclose Trade Secrets to the Government or to other Consortium Member(s) in connection with the Research Projects. Neither the Government nor the Consortium, the CM nor any Consortium Member shall be obligated to transfer Proprietary Information or Trade Secrets independently developed to any other party.

8.3. Confidentiality and Authorized Disclosure. The Receiving Party agrees, to the extent permitted by law, that Proprietary Information and Trade Secrets shall remain the property of the Disclosing Party (no one shall disclose such information unless they have the right to do so), and that, unless otherwise agreed to by the Disclosing Party, Proprietary Information and Trade Secrets shall not be disclosed, divulged, or otherwise communicated by the Receiving Party to third parties (including without limitation, other Consortium Members) or used by the Receiving Party for any purposes other than in connection with the Research Projects and the licenses granted

in Articles 9 and 10; provided that the terms “Proprietary Information” and “Trade Secrets” shall exclude materials or information that:

- 8.3.1. Are received or become available without restriction to the Receiving Party under separate agreement;
- 8.3.2. Are not identified with a suitable notice or legend per Paragraph 8.1.3 herein;
- 8.3.3. Are in possession of the Receiving Party at the time of disclosure thereof as demonstrated by prior written records;
- 8.3.4. Are or later become part of the public domain through no fault of the Receiving Party;
- 8.3.5. Are received by the Receiving Party from a third Party having no obligation of confidentiality to the Disclosing Party that made the disclosure;
- 8.3.6. Are developed independently by the Receiving Party without use of Proprietary Information or Trade Secrets as evidenced by written records;
- 8.3.7. Are required by law or regulation to be disclosed; provided, however, that the Receiving Party has provided written notice to the Disclosing Party promptly so as to enable such Disclosing Party to seek a protective order or otherwise prevent disclosure of such information.

8.4. Return of Proprietary Information. Upon request by the Consortium or a Consortium Member that made a disclosure of Proprietary Information or Trade Secrets to the Government or another Consortium Member, the Consortium, the Government or the other Consortium Member shall promptly return all copies and other tangible manifestations of the Trade Secrets or Proprietary Information disclosed. Upon request by the Consortium, the Government, or another Consortium Member shall promptly return all copies and other tangible manifestations of the Proprietary Information disclosed by the Government. As used in this section, tangible manifestations include human readable media as well as magnetic and digital storage media.

8.5. Term. The obligations of the Receiving Party under this Article shall continue for a period of five (5) years after disclosure of the information provided, however, that in the case of a Consortium Member that withdraws, or is deemed to have withdrawn, pursuant to Article 14 Termination, the Receiving Party’s obligations with respect to such Consortium Members’ Trade Secrets or Proprietary Information shall continue as described in this section notwithstanding such Consortium Member’s withdrawal.

8.6. Flow down. The Base Agreement Awardee shall include this Article, suitably modified, to identify all parties, in all subawards. This Article shall, in turn, be included in all sub-tier subawards or other forms of lower tier agreements, regardless of tier. The government will be a third party in interest for purposes of this Article in any agreement where flow-down of rights and obligations is required.

ARTICLE 9. RIGHTS IN TECHNICAL DATA, COMPUTER SOFTWARE, AND COPYRIGHTS

9.1. General. This Rights in Technical Data and Computer Software Article is specifically tailored for this Base Agreement to address respective rights of the Government and the Consortium on behalf of Research Project Awardees to such Data and Computer Software as is owned, developed, to be developed or used by an actual or prospective Research Project Awardee (1) as identified in a Research Project Proposal submitted to the Government through the CM in response to a Request for Proposals, and (2) when such proposal is selected by the Government for funded performance and the Research Project Award is issued by the CM to that Research Project Awardee for performance of such Research Project Award.

9.2. Definitions.

9.2.1. "Commercial Computer Software" as used in the Article is defined in DFARS 252-227-7014(a)(1) (Jun 1995).

9.2.2. "Commercial Computer Software License" means the license terms under which commercial computer software and Data (as defined in this Agreement) is sold or offered for sale, lease or license to the general public.

9.2.3. "Computer Data Base" as used in this Agreement, means a collection of data recorded in a form capable of being processed by a computer. The term does not include computer software.

9.2.4. "Computer program" as used in this Agreement means a set of instructions, rules, or routines in a form that is capable of causing a computer to perform a specific operation or series of operations.

9.2.5. "Computer software" as used in this Agreement means computer programs, source code, source code listings, object code listings, design details, algorithms, processes, flow charts, formulae and related material that would enable the software to be reproduced, recreated or recompiled. Computer software does not include computer data bases or computer software documentation.

9.2.6. "Research Project Awardee Data" as used in this Article means Data developed or made by and in the course of performing identified assigned tasks by any Research Project Awardee.

9.2.7. "Data" as used in this Article of the Agreement, means computer software, computer software documentation, form, fit and function data, and technical data as defined in this Article.

9.2.8. "Form, fit and function data" means technical data that describes the required overall physical, functional and performance characteristics (along with the

qualification requirements, if applicable) of an item, component, or process to the extent necessary to permit identification of physically and functionally interchangeable items.

- 9.2.9. “Government purpose rights” means the rights to use, modify, duplicate or disclose the “Data” licensed with such rights under this Agreement within the Government for United States Government purposes only; and to release or disclose data outside the Government to any authorized persons pursuant to an executed non-disclosure agreement for such persons use, modification, or reproduction for United States Government purposes only. United States Government purposes include Foreign Military Sales purposes. Under this Agreement, the period of Government purpose rights shall be no less than five (5) years and during such time the Research Project Awardee developing or providing such Data to the Government with government purpose rights shall have the sole and exclusive right to use such Data for commercial purposes. In the event this Data is used to perform another Research Project Award issued to that Research Project Awardee under this Agreement during this five (5) year period, the period of government purpose rights shall be extended an additional five (5) years starting with the date of completion of performance of the additional Research Project Award.
- 9.2.10. “Limited rights” as used in this Article is as defined in DFARS 252.227-7013(a)(13) (Nov 1995).
- 9.2.11. “Regulatory Application” as used in this Article is an investigational new drug application (IND), investigational device exemption (IDE), new drug application (NDA), biologics license application (BLA), premarket approval application (PMA), or 510(k) pre-market notification filing (510(k)) or another regulatory filing submitted or planned for submission to the U.S. Food and Drug Administration (FDA) related to the research under a Research Project Award.”
- 9.2.12. “Restricted rights” as used in this Article is as defined in DFARS 252.227-7014(a)(14) (Jun 1995).
- 9.2.13. “Small Business Innovated Research (SBIR) data rights” as used in this Article is as defined in DFARS 252.227-7018(a)(19).
- 9.2.14. “Specially Negotiated License Rights” are those rights to Data that have been specifically negotiated between the Government and the CM on behalf of the Research Project Awardee whose proposal is selected by the Government under a call for proposals issued under the Agreement.
- 9.2.15. “Technical data” means recorded information, regardless of the form or method of the recording, of a scientific or technical nature (including computer software

documentation). The term does not include computer software or data incidental to contract administration, such as financial and/or management information.

9.2.16. "Unlimited rights" means the rights to use, modify, duplicate, release, or disclose Data, in whole or in part, in any manner, and for any purpose whatsoever, and to have or authorize others to do so.

9.3. Data Categories

9.3.1. Category A is the Data developed and paid for totally by private funds, or the Research Project Awardee (or its subawardee's) IR&D funds and it is Data to which the Government has "Limited" or "Restricted" rights. Category A Data shall include, but not be limited to,

(a) Data as defined in this Article and any designs or other material provided by the Research Project Awardee for a Research Project Award under this Agreement which was not developed in the performance of work under that Research Project Award, and for which the Government has "Limited" or "Restricted" rights.

(b) Any initial Data or technical, marketing, or financial Data provided at the onset of the Research Project Award by any of the Research Project Awardees. Such Data shall be marked "Category A" and any rights to be provided to the Government for such Data under a specific Research Project Award shall be as identified in the proposal submitted to the Government and included into the Project Approval Letter and Research Project Awards.

9.3.2. Category B is any Data developed previously or under this Agreement with mixed funding, i.e. development was accomplished partially with Government funding under this Agreement. Any Data developed outside of the Research Project Award whether or not developed with any Government funding in whole or in part under a Government agreement, contract or subaward shall have the rights negotiated under such prior agreement, contract or subaward; the Government shall get no additional rights in such Data.

9.3.3. Category C is any Data developed exclusively with Government funds under this Agreement. Research and Development performed was not accomplished exclusively or partially at private expense. Under this category,

(a) the Government will have Unlimited Rights in Data developed exclusively with Government funds under a Research Project Award funded by the Government under this Agreement that is:

(i) Data pertaining to an item, component, or process which has been or will be developed exclusively with Government funds;

(ii) Studies, analyses, test data, or similar data produced for this contract, when the study, analysis, test, or similar work was specified as an element of performance;

(iii) Data created in the performance of the Agreement that relates to the development, manufacture, construction, or production of items, components, or processes;

(iv) Form, fit, and function data;

(v) Data necessary for installation, operation, maintenance, or training purposes (including detailed manufacturing or process data);

(vi) Corrections or changes to technical data furnished to the Contractor by the Government;

(vii) Otherwise publicly available or have been released or disclosed by the Research Project Awardee or Subawardee without restrictions on further use, release or disclosure, other than a release or disclosure resulting from the sale, transfer, or other assignment of interest in the technical data to another party or the sale or transfer of some or all of a business entity or its assets to another party;

(viii) Data in which the Government has obtained unlimited rights under another Government contract or as a result of negotiations; or

(ix) Data furnished to the Government, under this or any other Government contract or subaward thereunder, with—

(A) Government purpose license rights or limited rights and the restrictive condition(s) has/have expired; or

(B) Government purpose rights and the Contractor's exclusive right to use such data for commercial purposes has/have expired.

(x) Data included in any Regulatory Application, as defined in Article 9.2.11, or comprising a component thereof”

(b) However, any Data developed outside of this Agreement whether or not developed with any Government funding in whole or in part under a Government agreement, contract or subaward shall have the rights negotiated under such prior agreement, contract or subaward; the Government shall get no additional rights in such Data.

(c) Further, the Government's rights to Commercial Computer Software and Data licensed under a Commercial Computer Software License under this Agreement,

and the treatment of Data relating thereto, shall be as set forth in the Commercial Computer Software License.

9.3.4. Category D is any Data developed under any specifically-negotiated data rights agreement consistent with paragraph 9.9 of this article. Any data developed under a specifically-negotiated data rights agreement will have the character and rights specified therein and may be flexible to meet the needs of the parties. Any such specifically-negotiated data rights agreement will be included in the associated Research Project Award. Specifically-negotiated data rights are the exception to the standard Categories A, B and C data described in the forgoing paragraphs. Absence of specifically-negotiated data rights in the Research Project Award will render the data rights allocated consistent with the forgoing paragraphs.

9.3.5. The Government can only order such Data as is developed under the Research Project Award where the order request is made within one (1) year following Research Project Award completion. In the event the Government orders such Data, it shall pay CM or Research Project Awardee the reasonable costs for all efforts to deliver such requested Data, including but not limited to costs of locating such Data, formatting, reproducing, shipping, and associated administrative costs.

9.3.6. The parties to this Agreement understand and agree that the CM shall have its Research Project Awardees stamp all documents in accordance with this Article and that the Freedom of Information Act (FOIA) and Trade Secrets Act (TSA) apply to Data.

9.4. Allocation of Principal Rights

9.4.1. The Government shall have "limited" or "restricted" rights to Category A Data.

9.4.2. The Government shall normally have immediate Unlimited or Government Purpose License Rights to Category B or C Data upon Research Project completion, except that

(a) for Article 9 Category C Data, the Government shall have only the rights established under prior agreements.

(b) for Article 9 Category C Data, the Government shall only have the rights set forth in the Commercial Computer Software Data license agreement.

9.4.3. Data that will be delivered, furnished, or otherwise provided to the Government as specified in a specific Research Project Award funded under this Agreement, in which the Government has previously obtained rights, shall be delivered, furnished, or provided with the pre-existing rights, unless (a) the parties have agreed otherwise, or (b) any restrictions on the Government's rights to use, modify,

reproduce, release, perform, display, or disclose the data have expired or no longer apply.

9.4.4. Each proposal submitted by the CM on behalf of an individual or team of Research Project Awardees in response to a Government call for proposals under this Agreement shall include a list of the Category A, B and C Data to be used or developed under the proposal if selected. Rights in such Data shall be as established under the terms of this Agreement, unless otherwise asserted in the proposal and agreed to by the Government. The AO will incorporate the list of Category A, B and C Data and the identified rights therefor in the award document.

9.4.5. Following issuance of an Project Approval Letter, pOTA Task Order, and subsequent CM issuance of the Research Project Award, the CM on behalf of the Research Project Awardee shall update the list to identify any additional, previously unidentified, Data if such Data will be used or generated in the performance of the funded work. Rights in such Data shall be as established under the terms of this Agreement, unless otherwise asserted in a supplemental listing and agreed to by the Government.

9.5. Marking of Data

9.5.1. Except for Data delivered with unlimited rights, Data to be delivered under this Agreement subject to restrictions on use, duplication or disclosure shall be marked with the following legend:

Use, duplication, or disclosure is subject to the restrictions as stated in the Agreement between the U.S. Government and the Consortium, Agreement No. W81XWH-15-9-0001, Proposal Title with [insert name of company] No. _____.

9.5.2. It is not anticipated that any Category A Data will be delivered to the Government under this Agreement.

9.5.3. In the event commercial computer software and Data is licensed under a commercial computer software license under this Agreement, a Special License rights marking legend shall be used as agreed to by the parties.

9.5.4. The Government shall have unlimited rights in all unmarked Data. In the event that an Research Project Awardee learns of a release to the Government of its unmarked Data that should have contained a restricted legend, the CM on behalf of the Research Project Awardee will have the opportunity to cure such omission going forward by providing written notice to the AO within three (3) months of the erroneous release.

9.6. Copyright

- 9.6.1. The CM on behalf of the Research Project Awardees reserves the right to protect by copyright original works developed under this Agreement. All such copyrights will be in the name of the individual Research Project Awardee(s). The Research Project Awardee hereby grants to the U.S. Government a non-exclusive, non-transferable, royalty-free, fully paid-up license to reproduce, prepare derivative works, distribute copies to the public, and perform publicly and display publicly, for governmental purposes, any copyrighted materials developed under this agreement, and to authorize others to do so.
- 9.6.2. In the event Data is exchanged with a notice indicating that the Data is protected under copyright as a published, copyrighted work and it is also indicated on the Data that such Data existed prior to, or was produced outside of this Agreement, the Party receiving the Data and others acting on its behalf may reproduce, distribute, and prepare derivative works for the sole purpose of carrying out that Party's responsibilities under this Agreement with the written permission of the Copyright holder.
- 9.6.3. Except that copyrighted Data that existed or was produced outside of this Agreement and is unpublished - having only been provided under licensing agreement with restrictions on its use and disclosure - and is provided under this Agreement shall be marked as unpublished copyright in addition to the appropriate license rights legend restricting its use, and treated in accordance with such license rights legend markings restricting its use.
- 9.6.4. The Research Project Awardees are responsible for affixing appropriate markings indicating the rights of the Government on all Data delivered under this Agreement.
- 9.6.5. The Government agrees not to remove any copyright notices placed on Data and to include such notices on all reproductions of the Data.

9.7. Data First Produced by the Government

9.7.1. As to Data first produced by the Government in carrying out the Government's responsibilities under this Agreement and which Data would embody trade secrets or would comprise commercial or financial information that is privileged or confidential if obtained from the CM on behalf of any Research Project Awardee, such Data will, to the extent permitted by law, be appropriately marked with a suitable notice or legend and maintained in confidence by the CM and any Research Project Awardee to whom disclosed for three (3) years after the development of the information, with the express understanding that during the aforesaid period such Data may be disclosed and used by the CM or Research Project Awardee, including its respective employees or subawards of any tier, (under suitable protective conditions) by or on behalf of the Government for Government purposes only.

9.8. Prior Technology

9.8.1. Government Prior Technology: In the event it is necessary for the Government to furnish the CM or any Research Project Awardee, including their respective employees or their subawards of any tier, with Data which existed prior to, or was produced outside of this Agreement, and such Data is so identified with a suitable notice or legend, the Data will be maintained in confidence and disclosed and used only for the purpose of carrying out their responsibilities under this Agreement. Data protection will include proprietary markings and handling, and the signing of non-disclosure agreements by the CM, Research Project Awardees, or subawards of any tier and their respective employees to whom such Data is provided for use under the Agreement. Upon completion of activities under this Agreement, such Data will be disposed of as requested by the Government.

9.8.2. CM and Research Project Awardee: In the event it is necessary for the CM or Research Project Awardee to furnish the Government with Data which existed prior to, or was produced outside of this Agreement, and such Data embodies trade secrets or comprises commercial or financial information which is privileged or confidential, and such Data is so identified with a suitable notice or legend, the Data will be maintained in confidence and disclosed and used by the Government and such Government Contractors or contract employees that the Government may hire on a temporary or periodic basis only for the purpose of carrying out the Government's responsibilities under this Agreement. Data protection will include proprietary markings and handling, and the signing of nondisclosure agreements by such Government Contractors or contract employees. Neither the CM nor Research Project Awardee shall be obligated to provide Data that existed prior to, or was developed outside of this Agreement to the Government. Upon completion of activities under this Agreement, such Data will be disposed of as requested by the CM on behalf of itself or Research Project Awardees.

9.8.3. Oral and Visual Information: If information which the CM, Research Project Awardees, or their subawards of any tier and their respective employees considers to embody trade secrets or to comprise commercial or financial information which is privileged or confidential is expressly disclosed orally or visually directly to the Government, the exchange of such information must be memorialized in tangible, recorded form and marked with a suitable notice or legend, and furnished to the Government within ten (10) calendar days after such oral or visual disclosure, or the Government shall have no duty to limit or restrict, and shall not incur any liability for any disclosure and use of such information. Upon Government request, additional detailed information about the exchange will be provided subject to restrictions on use and disclosure.

9.8.4. Disclaimer of Liability: Notwithstanding the above, the Government shall not be restricted in, nor incur any liability for, the disclosure and use of:

(a) Data not identified with a suitable notice or legend as set forth in this Article; nor

(b) Information contained in any Data for which disclosure and use is restricted under Article 8 entitled "Proprietary Information" above, if such information is or becomes generally known without breach of the above, is properly known to the Government or is generated by the Government independent of carrying out responsibilities under this Agreement, is rightfully received from a third party without restriction, or is included in Data which the CM or Research Project Awardee has furnished, or is required to furnish to the Government without restriction on disclosure and use. Information designated as Confidential or "Proprietary Information" shall not be disclosed, copied, reproduced, or otherwise made available in any form whatsoever to any other person, firm, corporation, partnership, association, or other entity without the consent of the Collaborator except as such information may be subject to disclosure under the Freedom of Information Act (5 U.S.C. 552).

9.8.5. Marking of Data: Any Data delivered under this Agreement shall be marked with a suitable notice or legend.

9.9. Negotiating Other Rights. Notwithstanding the Paragraphs in this Article, differing rights in Data may be negotiated among the Parties to each individual Research Project Award on a case-by-case basis.

9.10. Flow down. The Research Project Awardee shall include this Article, suitably modified, to identify all parties, in all subawards. This Article shall, in turn, be included in all sub-tier subawards or other forms of lower tier agreements, regardless of tier. The government will be a third party in interest for purposes of this Article in any agreement where flow-down of rights and obligations is required.

9.11. Survival Rights. Provisions of this Article shall survive termination of this Agreement under Article 13. Notwithstanding the terms of this in this Article, differing rights in data may be negotiated among the Parties to each individual Research Project Award on a case-by-case basis.

ARTICLE 10. INVENTIONS

10.1. Patent Rights. Patent Rights for work funded by this Agreement shall be substantially the same as FAR 52.227-11 (“Patent Rights – Ownership by the Contractor {May 2014}”), <https://www.acquisition.gov/far/>, which is hereby incorporated by reference with the following modifications. With respect to Patent Rights, the Government acknowledges and agrees that its rights will depend upon its financial contributions. If the Government contributes between 0-49% of the Research Project Award costs, the Government shall obtain a nonexclusive, nontransferable, irrevocable, paid up license to practice, or have practiced for or on its behalf, for government purposes, the subject invention throughout the world. If the Government contributes between 50%-100% of the Research Project Award costs, the Government shall obtain the same license rights with the ability to transfer the license for commercial purposes. In addition, the following modification to FAR 52.227-11, Subclause (b) “Contractor’s rights” is made

10.1.1. Government Employee Inventions. The Parties agree that the U.S. Government shall have the initial option to retain title to each Subject Invention made only by its employees. The Government shall promptly notify the Consortium and Consortium Members upon making this election, and in the event that the Government informs the Consortium and Consortium Members that it elects to retain title to such Subject Invention, the Government agrees to timely file patent applications thereon at its own expense. The Government agrees to enter into negotiations in good faith with the Consortium and Consortium Members for a license to Consortium or Consortium Members of the Government’s interests to the invention within specified fields of use, at reasonable rate, terms, and conditions. Any such license agreement shall be subject to a nonexclusive, nontransferable, irrevocable, paid-up license to practice the invention or have the invention practiced throughout the world by or on behalf of the Government. The Government may release the rights provided for by this paragraph to its employee inventors subject to any license to the Consortium and Consortium Members as described above.

10.1.2. Joint Employee Inventions. Title to Subject Inventions made jointly by employees of the Government and Consortium or Consortium Members shall be held jointly by the Government and Consortium or Consortium Members. Consortium or Consortium Members shall have the initial option to file patent applications on joint Subject Inventions at its own expense.

10.1.2.1. In the event that the Consortium or Consortium Members decline to file or complete prosecution of such patent application, Consortium or Consortium Members waive its co-ownership interest and agree to assign its title to such joint Subject Inventions to the Government in exchange for a non-exclusive, irrevocably paid-up license to practice such Subject Invention throughout the world.

10.1.2.2. In the event that Consortium or Consortium Members elect to file and complete prosecution of such patent applications, the Government agrees to enter into negotiations in good faith with Consortium or Consortium Members for a license to Consortium or Consortium Members of the Government's interests to the invention within specified fields of use, at reasonable rate, terms, and conditions. Any such license agreement shall be subject to a nonexclusive, nontransferable, irrevocable, paid-up license to practice the invention or have the invention practiced throughout the world by or on behalf of the Government.

10.1.2.3. Government reserves the right to ensure that any license it grants to the Consortium or Consortium Members is consistent with the Government's international treaty and agreement obligations.

10.1.2.4. Consortium or Consortium Members shall notify the Government in writing of its interest in obtaining such exclusive license rights within thirty (30) days of Subject Invention filing.

10.2. Patent Reports. The Consortium or Consortium Members shall file Invention (Patent) Reports as of the close of the performance year and at the end of each project award for this Agreement or more frequently if a statutory bar will occur before the next annual or final project report. Annual reports are due sixty (60) calendar days after the expiration of the final performance period. The Research Project Awardee shall use DD Form 882, Report of Inventions and Subawards (or forms appropriate to non DoD agencies), to file an invention report. Such reports are required whether or not a Subject Invention was made. The patent recipient Consortium Member(s) shall submit the original and one copy to the AO, through the CM, and one copy to the technology scientist or engineer.

10.3. Authorization and Consent. The Government authorizes and consents under 28 U.S.C. 1498 to all use and manufacture of any invention described in and covered by a United States patent in the performance of this Agreement or any subaward at any tier.

10.4. Final Payment. Final payment cannot be made nor can the Agreement be closed-out until the patent recipient, Consortium or Consortium Members deliver to the Government all disclosures of Subject Inventions required by this Agreement, an

acceptable final report pursuant to the article entitled "Reports," and all confirmatory instruments.

- 10.5. Cooperation.** The Government and the Consortium and/or Consortium Members shall keep the other informed as to the status of joint patent matters. The Government and the Consortium and/or Consortium Members shall each reasonably cooperate with and assist the other at its own expense in connection with such activities, at the other Party's request during the term of this Agreement.
- 10.6. Flow down.** The Base Agreement Awardee shall include this Article, suitably modified, to identify all parties, in all subawards. This Article shall, in turn, be included in all sub-tier subawards or other forms of lower tier agreements, regardless of tier. The government will be a third party in interest for purposes of this Article in any agreement where flow-down of rights and obligations is required.
- 10.7. Differing Patent Rights.** Notwithstanding Paragraphs 10.1 through 10.5 above, differing patent rights may be negotiated among the Parties to each individual Research Project Award on a case-by-case basis.

ARTICLE 11. EXPORT CONTROLS

- 11.1. Export Compliance.** Each Party agrees to comply with U.S. Export regulations including, but not limited to, the requirements of the Arms Export Control Act, 22 U.S.C. § 2751-2794, including the International Traffic in Arms Regulation (ITAR), 22 C.F.R. § 120 et seq.; and the Export Administration Act, 50 U.S.C. app. § 2401-2420. Each party is responsible for obtaining from the Government export licenses or other authorizations/approvals, if required, for information or materials provided from one party to another under this Agreement. Accordingly, the Base Agreement Awardee shall not export, directly, or indirectly, any products and/or technology, Confidential Information, Trade Secrets, or Classified and Unclassified Technical Data in violation of any U.S. Export laws or regulations.
- 11.2. Foreign Nationals.** The Government acknowledges and encourages the Consortium to be open to membership from foreign organizations that perform research within the scope of this Agreement. Therefore, the government will indicate, both in solicitations and with the issuance of a Research Project Award, whether or not the technology being developed is subject to national security restrictions. Additionally, when soliciting MTEC members through the CM, the Government will ensure that solicitations documents do not contain any export-controlled information. Solicitations that require access to export-controlled information will be identified as such and contain instructions on how Consortium members may obtain this information. Only MTEC members who have completed a DD Form 2345 and are active in the Joint Certification Program shall be provided export-controlled information.

11.3. Flow down. The Base Agreement Awardee shall include this Article, suitably modified to identify all parties, in all or subawards. This Article shall, in turn, be included in all sub-tier subawards or other forms of lower tier agreements, regardless of tier. The government will be a third party in interest for purposes of this Article in any agreement where flow-down of rights and obligations is required.

ARTICLE 12. PUBLICATION AND ACADEMIC RIGHTS

12.1. Use of Information. Subject to the provisions of Paragraph 12.3, the Consortium and the Consortium Members (and their employees) and the Government (and its employees) shall have the right to publish or otherwise disclose information and/or data developed by the Government, the Consortium and/or Consortium Members under a Research Project Award or Subaward. The Consortium and Consortium Members (and their employees) and the Government (and its employees) shall include an appropriate acknowledgement of the sponsorship of the Research Project Award and or Subaward by the Government, the Consortium and/or other Consortium Members in such publication or disclosure. The Parties shall have the right to use, disclose, and exploit any such data and information in accordance with the rights held by them pursuant to this Agreement. Notwithstanding the above, it is the intention of the Parties that no Proprietary Information or proprietary information shall be disclosed through this process.

12.2. Oral and Visual Information. If oral or visual presentation of information from a Research Project Award or subaward is made to an external organization, then the Research Project Awardee must notify the CM in writing 45 days in advance identifying the organization to which the presentation is to be made, the benefit of the presentation to the program, and any associated risks with presenting the information to the external group and any costs to the Government that will be incurred. All oral or visual presentation of information shall have appropriate disclaimers.

12.3. Publication or Public Disclosure of Information.

12.3.1. Classified Research Projects. If a release of information is for a classified Research Project Award, the provisions of the DoD Security Agreement (DD Form 441) and the DoD Contract Security Classification Specification (DD Form 254) apply (or forms appropriate to other Government agencies).

12.3.2. Clearance of Technical Information for Public Release.

12.3.2.1. Disclosure of unclassified Research Projects shall be in accordance with the applicable Distribution Statement.

12.3.2.2. Approval of the Agreements Officer is not required prior to the release of information received in the performance of a Research Project Award or developed pursuant to a Subaward if the a Research Project Award or Subaward is awarded to a college, university or laboratory and the research work is performed on campus, except that such approval shall be obtained prior to the release of information where there is a high likelihood of disclosing performance characteristics of military systems or information concerning manufacturing technologies unique and critical to defense.

12.3.2.3. Parties to this Agreement are responsible for assuring that an acknowledgment of Government support will appear in any publication of any material based on or developed under this Agreement, a Research Project Award, or a Subaward, in the following terms:

12.3.2.3.1. "Effort sponsored by the Government under Other Transactions Number W81XWH-15-9-0001;

12.3.2.3.2. The U.S. Government is authorized to reproduce and distribute reprints for Governmental purposes notwithstanding any copyright notation thereon."

12.3.2.4. Parties to this Agreement, a Research Project Award or a Subaward, are responsible for assuring that every publication of material based on or developed contains the following disclaimer:

"The views and conclusions contained herein are those of the authors and should not be interpreted as necessarily representing the official policies or endorsements, either expressed or implied, of the U.S. Government."

12.4. Notices. To avoid disclosure of Proprietary Information or Trade Secrets belonging to the Consortium, a Consortium Member and/or the Government and the loss of patent rights as a result of premature public disclosure of patentable information, the Party that is proposing to publish or disclose such information, agrees to provide notice to both the Party to whom such Proprietary Information or Trade Secrets belongs and the Agreements Officer at least forty-five (45) calendar days prior to any submission for publication or disclosure, together with any and all materials intended for publication or disclosure relating to technical reports, data, or information developed by the Government, the Consortium and/or the Consortium Members during the term of and pursuant to this Agreement.

12.5. Filing of Patent Applications. During the course of any such ninety (90) calendar day period, the party to whom such Proprietary Information or Trade Secrets belongs

and/or Government shall provide notice to the AO whether it desires that a patent application be filed on any invention disclosed in such materials. In the event that the party to whom such Proprietary Information or Trade Secrets belongs and/or Government desires that such a patent application be filed, the Party proposing to publish or disclose such materials agrees to withhold publication and disclosure of such materials until the occurrence of the first of the following:

12.5.1. Filing of a patent application covering such invention, or

12.5.2. Written agreement, from the AO and Party to whom such Proprietary Information or Trade Secrets belongs, that no patentable invention is disclosed in such materials.

Further, during the course of any such ninety (90) calendar day period, any party who believes that any of its Proprietary Information or Trade Secrets have been included in the proposed publication or disclosure shall provide notice to the Party proposing to publish or disclose such materials of the extent of the Proprietary Information or Trade Secrets that should be removed from such proposed publication or disclosure. The Party proposing the publication or disclosure of such materials agrees to remove all such Proprietary Information or Trade Secrets from the proposed publication or disclosure.

12.6. Flow down. The Base Agreement Awardee shall include this Article, suitably modified to identify all parties, in all subawards. This Article shall, in turn, be included in all sub-tier subawards or other forms of lower tier agreements, regardless of tier. The government will be a third party in interest for purposes of this Article in any agreement where flow-down of rights and obligations is required.

ARTICLE 13. BASE AGREEMENT TERM AND TERMINATION

13.1. Term of the Agreement. The period of performance for this Agreement is from the the Effective Date, which is the date of last signature to January 25, 2026. Research Project Awards awarded pursuant to and during the term of this Agreement may continue beyond the expiration of this Agreement pursuant to the terms of such Research Project Award. Paragraphs in this Agreement, which by their express terms or by their necessary implication, apply for periods of time other than as specified in this paragraph, shall be given effect, notwithstanding this paragraph.

13.2. Termination of Base Agreement by Mutual Agreement. This Base Agreement and/or any resultant Research Project Awards shall terminate by mutual agreement and receipt of AO approval. Rights and obligations with respect to proprietary information and/or specific intellectual property agreements between or amongst the Government and the Consortium and Consortium Members shall survive any such mutual termination unless otherwise agreed to in writing.

- 13.3. Unilateral Termination.** Subject to a reasonable determination that this Agreement will not produce beneficial results commensurate with the expenditure of resources, either the CM, at the direction of Government, or the Base Agreement Awardee may terminate this Agreement by written notice to the other Party, provided that such written notice is preceded by consultation between the Government, Base Agreement Awardee, and CM. In the event of a termination of the Agreement, it is agreed that disposition of Data developed under this Agreement, shall be in accordance with the provisions set forth in Article 9, Rights in Technical Data, Computer Software, and Copyrights. The Parties will negotiate in good faith a reasonable and timely adjustment of all outstanding issues as a result of termination. Failure to agree to a reasonable adjustment will be resolved pursuant to Article 19, Dispute Resolution.
- 13.4. Renewal.** Not later than the end of the eighth Year, the Base Agreement Awardee and CM shall meet to consider a renewal of the term of this Agreement for an additional ten (10) Years. If the Parties so agree to such a renewal, they shall enter into an appropriate amendment of this Agreement reflecting the terms to be in effect during the renewal period.

ARTICLE 14. RESEARCH PROJECT AWARDS, TERM AND TERMINATION

- 14.1. Term.** The term of the Research Project Awards will be as stated in the terms and conditions of each individual Research Project Award.
- 14.2. Termination.** Any Research Project Award awarded pursuant to this Agreement may be terminated in whole or in part, upon prior consultation by the Parties and the expiration of thirty (30) calendar days following written notice to the Government, the Consortium and the Consortium Member or Members performing the Research Project Award, as set forth below:
- 14.2.1. By the AO, through the CM, should insufficient funds be available to accomplish the goals or intent of the Research Project Award or for other convenience to the Government. Such termination will be effective immediately upon written notice notwithstanding any prior notice requirement of this Agreement. In any event, thirty (30) calendar days prior written notice will be provided to the maximum extent practicable;
- 14.2.2. By the Parties, based on an agreement by the Government and Research Project Awardee that the Research Project will not produce beneficial results commensurate with the expenditure of resources;
- 14.2.3. By the AO, through the CM, with the consent of the other Parties. In this case the Parties shall agree upon the termination conditions, including the effective date and, in the case of partial termination, the portion to be terminated; or
- 14.2.4. By the Research Project Awardee, upon sending the AO through the CM, a written notification, setting forth the reasons for such termination, the effective date and,

in the case of partial termination, the portion to be terminated. The notice shall also include the total costs incurred or committed to date as well as projected costs for closeout. The Research Project Awardee must provide such notice at least sixty (60) calendar days prior to the effective date of the termination. No costs shall be incurred beyond those listed in the termination notice, unless otherwise agreed to by the Agreements Officer. Upon receipt of the termination notice, the AO in consultation with the SOTR, will determine the appropriate path forward, which may include a full or partial transfer of tasks to another Research Project Awardee or Government entity, full or partial termination of the Research Project Award, or other mutual agreement between the Parties. If the AO determines, in the case of partial termination, that the reduced or modified portion of the Research Project Award will not accomplish the purposes for which the Research Project Award was awarded, the AO, through the CM, may terminate the Research Project Award in its entirety.

14.3. Termination Caused By Material Breach by the Research Project Awardee. If the Research Project Awardee materially fails to comply with the provisions of a Research Project Award, the AO, after issuance of a Cure Notice through the CM and failure of the Research Project Awardee to cure the defect within ten (10) days or the time allowed by the AO after receipt of the cure notice, may take one or more of the following actions as appropriate:

- 14.3.1. Temporarily withhold payments pending correction of the deficiency;
- 14.3.2. Disallow all or part of the cost of the activity or action not in compliance;
- 14.3.3. Wholly or partly suspend or terminate the current Research Project Award;
- 14.3.4. Withhold further funding for the Research Project Award;
- 14.3.5. Take any other legally available remedies.

14.4. Termination Costs. The Parties will negotiate in good faith an equitable reimbursement for work performed toward accomplishment of the task or tasks in the SOW of the Research Project Award. The Government will allow full credit to the Research Project Awardee for the Government share of the obligations properly incurred by the Research Project Awardee prior to termination. Costs incurred during a suspension or after termination of a Research Project Award are not allowable unless the AO, through the CM, expressly authorizes them in either the notices of suspension, termination or subsequently. Other costs incurred during a suspension or after termination which are necessary and not reasonably avoidable are allowable if:

- 14.4.1. The costs result from obligations which were properly incurred by the Research Project Awardee before the effective date of the suspension or termination, are not in anticipation of it, and in the case of a termination, are non-cancellable; and

14.4.2. The costs would be allowable if the award was not suspended or the award expired normally at the end of the funding period in which the termination takes effect.

14.5. Close-out Procedures. If this Agreement and/or any Research Project Awards issued pursuant to this Agreement are completed or terminated, the following closeout procedures apply.

14.5.1. Definitions

14.5.1.1. “Close-out” – is the process by which the Government determines that all applicable administrative actions and all required work have been completed by the Research Project Awardee and the Government.

14.5.1.2. “Date of Completion” – is the date on which all work is completed or the date on the Research Project Awards or an amendment thereto on which the period of performance ends.

14.5.1.3. “Disallowed costs” – are those charges to the Research Project Award that the Government or its representative determines to be unallowable, in accordance with the terms and conditions stated in this Agreement.

14.5.2. Upon request, the Government shall make prompt payments to the Consortium for allowable reimbursable costs under the Research Project Award being closed out.

14.5.3. The Government shall obtain from the Research Project Awardee through the CM within ninety (90) calendar days after the date of completion of the Research Project Award all financial, performance, and other reports required as the condition of the Research Project Award. The Government may grant extensions when requested by the CM on behalf of the Research Project Awardee.

14.5.4. When authorized by the Research Project Award, the Government, through the CM, shall make a settlement for any upward or downward adjustments to the Government’s share of costs, not to exceed the Government’s obligated cost share amount, after these reports are received.

14.5.5. Quick close-out procedures similar to FAR 42.708 shall be followed when possible.

14.5.6. The Research Project Awardee, through the CM, shall account for any property received from the Government.

ARTICLE 15. STOP WORK

15.1. As directed by the Government Agreement Officer, the CM may, at any time, by written order to the Research Project Awardee, require the Research Project Awardee to stop

all, or any part, of the work called for under any Research Project Award for a period of ninety (90) days after the written order is delivered to the Research Project Awardee, and for any further period to which the Parties may agree. The order shall be specifically identified as a stop-work order issued under this Article. Upon receipt of the order, the Research Project Awardee shall immediately comply with its terms and take all reasonable steps to minimize the incurrence of costs allocable to the work covered by the order during the period of work stoppage. Within a period of ninety (90) days after a stop-work is delivered to the Research Project Awardee, or within any extension of that period to which the Parties shall have agreed, the CM shall either:

15.1.1. Cancel the stop-work order; or

15.1.2. Terminate the work covered by the Research Project Award.

15.2. If a stop work order issued under this clause is canceled, the Research Project Awardee shall resume work. The Government, through the CM, shall make an equitable adjustment in the delivery schedule or Research Project Award estimated cost/price, or both, and the Government's share of the Research Project Award shall be modified, in writing, accordingly, if—

15.2.1. The stop-work order results in an increase in the time required for, or in the Research Project Awardee's cost properly allocable to, the performance of any part of the Research Project Award; and

15.2.2. The Research Project Awardee asserts its right to the adjustment within thirty (30) days after the end of the period of work stoppage; provided that, if the Government decides the facts justify the action, the Government, through the CM, may receive and act upon a proposal submitted at any time before final payment under the Research Project Award.

15.3. If a stop work order is not canceled and the work covered by the Research Project Award is terminated in accordance with Article 14 Research Project Awards, Term and Termination, the CM shall work with the Research Project Awardee to negotiate an equitable reimbursement in accordance with Article 14.4.

15.4. Flow down. The Research Project Awardee shall include this Article, suitably modified to identify all parties, in all subawards. This Article shall, in turn, be included in all sub-tier subawards or other forms of lower tier agreements, regardless of tier. The government will be a third party in interest for purposes of this Article in any agreement where flow-down of rights and obligations is required.

ARTICLE 16. NONTRADITIONAL DEFENSE CONTRACTORS / NONPROFIT RESEARCH INSTITUTION / COST SHARING

- 16.1.** Each Research Project Award must have at least one Nontraditional Defense Contractor or Nonprofit Research institution participating to a significant extent in the performance of an awarded Research Project Award or provide cost share of no less than one third of the value of the Research Project Award awarded to the Research Project Awardee. Examples of what might be considered a significant extent or significant contribution include, but may not be limited to supplying new key technologies or products, accomplishing a significant amount of the effort, or in some other way causing a material reduction in the cost or schedule or increase in the performance. Throughout the period of performance of any Project Research Project Award, the CM, AO, and SOTR will actively monitor Nontraditional Defense Contractor or Nonprofit Research Institution participation and/or cost sharing to ensure compliance with this provision in accordance with implementation guidance from HQDA and/or OSD. Research Project Awardees will be given the opportunity to become compliant with the guidance should they be found non-compliant. Failure to comply may result in termination.
- 16.2. Cost Sharing Arrangement Adjustment.** If a Research Project Award is performed under budget or the Research Project Awardee does not expect to contribute its specified share, the Government will review the share ratio to determine whether the Government's share is still equitable or whether the Government's share should be reduced based upon the revised circumstances. Costs will be evaluated based upon the terms and conditions contained in the Research Project Award.
- 16.3. Cost Sharing Liability.** The Research Project Awardee's liability to fund the Research Project Award shall be limited to the total "Research Project Awardee's Share" value identified in the pOTA Task Order or Project Approval Letter (PAL) and identified by the CM in a Research Project Award. If a Research Project Awardee exceeds the amount of cost share identified in a Research Project Award, neither the Government nor the CM will be obligated to increase the Government funding for the project.

ARTICLE 17. REPRESENTATIONS AND WARRANTIES

- 17.1. Representations and Warranties of All Parties.** Each Party to this Agreement represents and warrants to the other Parties that:
- 17.1.1. It is a validly existing legal or Government entity;
 - 17.1.2. It is free to enter into this Agreement;
 - 17.1.3. In so doing, it will not violate any other agreement to which it is a Party; and
 - 17.1.4. It has taken all action necessary to authorize the execution and delivery of this Agreement and the performance of its obligations under this Agreement.
- 17.2. Limitations.** Except as expressly provided herein, neither the Consortium nor the Government makes any warranty, express or implied, either in fact or by operation of

law, by statute or otherwise, relating to (a) any research conducted under this Agreement or (b) any invention conceived and/or reduced to practice under this Agreement or (c) any other intellectual property developed under this Agreement, and each one specifically disclaims any implied warranty of merchantability or warranty of fitness for a particular purpose.

- 17.3. Flow down.** The Base Agreement Awardee shall include this Article, suitably modified to identify all parties, in all subawards. This Article shall, in turn, be included in all sub-tier subawards or other forms of lower tier agreements, regardless of tier. The government will be a third party in interest for purposes of this Article in any agreement where flow-down of rights and obligations is required.

ARTICLE 18. LIABILITY OF THE PARTIES

- 18.1. Waiver of Liability.** With regard to the activities undertaken pursuant to this Agreement, no Party shall make any claim against another Party, another Party's employees, another Party's related entities (e.g., contractors, Subawardees, etc.) or employees of another Party's related entities for any injury to or death of its own employees or employees of its related entities, or for damage to or loss of its own property or that of its related entities, whether such injury, death, damage, or loss arises through negligence or otherwise, except in the case of willful misconduct.
- 18.2. Damages.** To the extent that a risk of damage or loss is not dealt with expressly in this Agreement, the Parties liability to the other Parties arising out of this Agreement whether or not arising as a result of an alleged breach of this Agreement, shall be limited to direct damages only, and shall not include any consequential, punitive, special and incidental damages, claims for lost profits, or other indirect or consequential damages.
- 18.3. Extension of Waiver of Liability.** Research Project Awardees, and subcontractors at any tier agree to waive all claims against any and all Parties to this Agreement or sub-tier award.
- 18.4. Applicability.** Notwithstanding the other provisions of this article, this waiver of liability shall not be applicable to:
- 18.4.1. Claims between the Parties regarding a material breach or non-payment of funds for a Research Project Award,
 - 18.4.2. Claims for damage caused by willful misconduct,
 - 18.4.3. IP claims.
- 18.5. Limitation of Liability.** In no case shall the Government's, the CM's or the Consortium's financial liability exceed the amount obligated by the Government or committed as a Cash Contribution or In-kind Contribution by a Research Project Awardee. Nothing in

this Article shall be construed to create the basis of a claim or suit where none would otherwise exist.

- 18.6. Flow down.** The Base Agreement Awardee shall include this Article, suitably modified to identify all parties, in all subawards. This Article shall, in turn, be included in all sub-tier subawards or other forms of lower tier agreements, regardless of tier. The government will be a third party in interest for purposes of this Article in any agreement where flow-down of rights and obligations is required.

ARTICLE 19. DISPUTE RESOLUTION

- 19.1. General.** For the purposes of this Article, “Parties” means the CM, the Research Project Awardee and the Government where collectively identified and “Party” where each entity is individually identified. The Parties shall communicate with one another in good faith and in a timely and cooperative manner when raising issues under this Article.

- 19.2. Dispute Resolution Process.** The Parties recognize that disputes relating to their rights and obligations hereunder may arise from time to time during the term of this Agreement or during performance of a Research Project Award awarded under this Agreement. It is the objective of the Parties to establish procedures to facilitate the resolution of disputes arising under this Agreement and any Research Project Award in an expeditious manner by mutual cooperation. To accomplish this objective, the Parties agree to follow the procedures set forth in this Article if and when a dispute arises under this Agreement or any Research Project Award awarded pursuant to this Agreement.

19.2.1. Whenever disputes, disagreements, or misunderstandings arise, the Parties shall attempt to resolve the issue(s) involved by discussion and mutual agreement as soon as practicable. In no event shall a dispute, disagreement or misunderstanding which arose more than three (3) months prior to the notification made under this article constitute the basis for relief under this article unless the Principal Assistant Responsible for Contracting (PARC), in the interest of justice waives this requirement.

19.2.2. Failing resolution by mutual agreement, the aggrieved Party shall document the dispute, disagreement, or misunderstanding by notifying the other Party (through their respective AO or the CM representative as the case may be) in writing documenting the relevant facts, identifying unresolved issues, specifying the clarification or remedy sought, and documenting the rationale as to why the clarification/remedy is appropriate. Within ten (10) working days after providing notice to the other Party, the aggrieved Party may, in writing, request a decision by the PARC. The other Party shall submit a written position on the matter(s) in dispute within thirty (30) calendar days after being notified that a decision has been

requested. The PARC, will conduct a review of the matter(s) in dispute and render a decision in writing within thirty (30) calendar days of receipt of such position. Any such decision is final and binding, unless a Party shall, within thirty (30) calendar days request further review as provided by this article.

19.2.3. If requested within thirty (30) calendar days of the PARC's decision, further review will be conducted by the Principal Assistant for Research and Technology and the MTEC President. In the event of a decision, or in absence of a decision within sixty (60) calendar days of referral to the Principal Assistant for Research and Technology & MTEC President (or such other period as agreed to by the parties), either Party may pursue any right or remedy provided by law. Alternatively, the parties may agree to explore and establish an Alternate Disputes Resolution procedure to resolve this dispute.

19.3. Flow down. The Base Agreement Awardee shall include this Article, suitably modified to identify all parties, in all subawards. This Article shall, in turn, be included in all sub-tier subawards or other forms of lower tier agreements, regardless of tier. The government will be a third party in interest for purposes of this Article in any agreement where flow-down of rights and obligations is required.

ARTICLE 20. GENERAL PROVISIONS

20.1. Fees. It is understood that as the Government funds the Research Project Awards under this Agreement, the Government will not be constrained from the payment of an appropriate fee or profit for the R&D effort being accomplished by the Consortium, the Consortium Manager or Research Project Awardees. The fees shall be specific to the individual Research Project Award and negotiated on a project-by-project basis.

20.2. Regulatory Affairs. Development and production of medical products and processes may be regulated by the U.S. Food and Drug Administration (FDA) and Research involving FDA-regulated medical products in animal (non-clinical) or human (clinical) studies is regulated by other laws, directives, and regulations. Research Project Awards under this Agreement that involve work in support of or related to FDA approval of drugs, biologics, or medical devices will specify: (a) which party is the sponsor and/or applicant to FDA, (b) ensure Government access to all regulatory communications and meetings regarding the Research Project, and (c) ensure Government access to regulatory rights (including but not limited to sponsorship or holdership of a regulatory application and/or rights of reference thereto) in the event of the Research Project Awardee's product development abandonment or failure. Efforts conducted under this Agreement shall be done ethically and in accordance with all applicable laws, directives, and regulations.

20.3. Independent Contractors. The relationship of the Consortium and its Members established by the Consortium Member Agreement is that of independent contractors,

and nothing contained in this Agreement shall be construed to (a) give the Consortium or any Consortium Member hereto the power to direct or control the day to day activities of the Consortium or another Consortium Member hereto, (b) constitute the Consortium or Consortium Members as partners, joint ventures, co-owners or otherwise as participants in a joint or common undertaking, or (c) allow the Consortium or any of the Consortium Members hereto to create or assume any obligation on behalf of another Consortium Member hereto for any purpose whatsoever.

20.4. Parties Bound. This Agreement shall be binding upon and inure to the benefit of the Parties hereto, their respective successors, assigns, and legal representatives. Nothing herein shall be construed to give any Consortium Member or Research Project Awardee rights as a party to or third-party beneficiary of this Agreement.

20.5. Assignment.

20.5.1. This Agreement may not be assigned or transferred by any of the Parties hereto without the prior written consent of the other Parties; provided, however, that the Consortium or a Consortium Member may assign its rights and delegate its obligations (i) to any affiliate of the Consortium or such Consortium Member (although, in the event of any such assignment and delegation, the assigning Party shall remain primarily liable for its obligations hereunder) and (ii) to a purchaser of all or substantially all of the business of the Consortium or such Consortium Member to which this Agreement relates by merger, sale of assets, or otherwise.

20.6. Affiliates. The Parties hereto acknowledge that some Parties will carry out certain activities required or permitted pursuant to this Agreement through their affiliates. The Parties hereby represent and warrant that this Agreement shall be binding on their affiliates in accordance with this Agreement as if such affiliates were Parties to this Agreement. In the event that any Party to this Agreement is acquired by another company, the technology and programs of the acquiring company in existence at the time of such transactions shall not be subject to the Agreement.

20.7. Civil Rights Act. This Agreement is subject to the compliance requirements of Title VI of the Civil Rights Act of 1964 as amended (42 U.S.C. 2000-d) relating to the nondiscrimination in federally assisted programs.

20.8. Entire Agreement. This Agreement constitutes the entire and only agreement between the Parties relating to the subject matter hereof, and all prior negotiations, representations, agreements, and understandings are superseded hereby.

20.9. Further Assurances. At any time or from time to time, the Parties shall, at the request of the Consortium or the Government:

- 20.9.1. Deliver to the Consortium, the Government, or Research Project Awardees such records, data, or other documents consistent with the provisions of this Agreement;
- 20.9.2. Execute, and deliver, or cause to be delivered, all such assignments, consents, documents, or further instruments of transfer or license; and
- 20.9.3. Take or cause to be taken all such other actions, as any Party may reasonably deem necessary or desirable in order for the Party to obtain the full benefits of this Agreement and the transactions contemplated hereby.

20.10. Right to Develop Independently. Although it is the intent of the Parties to utilize this Agreement in the Government's award of its R&D activities in the Field, nothing will impair any Party's right to independently acquire, license, develop or have developed, utilize or otherwise exploit similar information and technology performing the same or similar functions as the information and technology which is the subject of the technical objectives or any other relevant planning, program and budgeting system documents.

20.11. Radioactive Materials. Research Project Awardees shall assure compliance with the provisions of Title 10 CFR 21. This regulation establishes procedures and requirements for implementation of Section 206 of the Energy Reorganization Act of 1974.

20.12. Recombinant DNA. By signing the award or accepting funds under the award, you assure that all work involving the use of recombinant DNA will be in compliance with guidance provided at <https://osp.od.nih.gov/biotechnology/biosafety-and-recombinant-dna-activities/>

20.13. Environmental Liability. The Research Project Awardee is responsible for achieving compliance with all environmental laws applicable to the work performed under this Agreement, including but not limited to any licenses and permit applications required under Federal, State, or local laws or regulations. The Research Project Awardee shall not name the United States, the Department of Army (DA), or any other Government agency, instrumentality or employee as an owner, operator or in any other capacity on any license or permit application required under environmental laws unless written consent is first obtained from an authorized agent of the Federal agency or instrumentality to be named.

20.14. Prohibition of Use of Human Cadavers.

Research, development, testing and evaluation (RDT&E), education or training activities involving human cadaveric specimens under a Research Project Award shall not begin until approval is granted in accordance with the Army Policy for Use of Human Cadavers for RDT&E, Education, or Training, 20 April 2012 (https://mrmc.amedd.army.mil/index.cfm?pageid=research_protections.overview).

The USAMRMC Office of Research Protections (ORP) is the Action Office (usarmy.detrick.medcom-usamrmc.other.hrpo@mail.mil) for this policy. Approval must be obtained from the USAMRMC ORP. Research Project Awardees must coordinate with the supporting/funding Army organization to ensure that proper approvals are obtained. ORP will issue written approvals to begin under separate notification to the Research Project Awardee, a copy of which shall be provided to the appointed SOTR. Written approval to proceed from the USAMRMC ORP is also required for any subaward that will use funds from a Research Project Award to conduct RDT&E, education or training involving human cadaveric specimens.

The Research Project Awardee must promptly report problems related to the conduct of the activity involving cadavers or the procurement, inventory, use, storage, transfer, transportation, and disposition of cadavers to the appointed SOTR who informs USAMRMC ORP. The Research Project Awardee must maintain complete records of the activity.

The USAMRMC or designees must be permitted to observe the activity upon request and/or audit activity records to ensure compliance with the approved protocol or applicable regulatory requirements.

Non-compliance with these terms and conditions may result in withholding of funds and/or the termination of the award.

20.15. Prohibition of Use of Human Subjects.

Research under this Agreement or Research Project Awards involving the use of human subjects, to include research involving the secondary use of human biospecimens and/or human data, cannot begin until the USAMRMC's ORP provides authorization that the research may proceed. The USAMRMC ORP will issue written approval to begin research under separate notification to the Research Project Awardee, a copy of which shall be provided to the appointed SOTR. Written approval to proceed from the USAMRMC ORP is also required for any Research Project Awardee (or lower tier subawards) that will use funds from this award to conduct research involving human subjects.

The USAMRMC ORP conducts site visits as part of its responsibility for compliance oversight. Accurate and complete study records must be maintained and made available to representatives of the USAMRMC as a part of their responsibility to protect human subjects in research. Research records must be stored in a confidential manner so as to protect the confidentiality of subject information.

The Research Project Awardee is required to adhere to the following reporting requirements:

Submission of substantive modifications to the protocol, continuing review documentation, and the final report as outlined in the USAMRMC ORP approval memorandum.

Unanticipated problems involving risks to subjects or others, subject deaths related to participation in the research, clinical holds (voluntary or involuntary), and suspension or termination of this research by the IRB, the institution, the Sponsor, or regulatory agencies, must be promptly reported to the USAMRMC ORP

Change in subject status when a previously enrolled human subject becomes a prisoner must be promptly reported to the USAMRMC ORP HRPO.

The knowledge of any pending compliance inspection/visits by the FDA, ORP, or other government agency concerning this clinical investigation or research, the issuance of Inspection Reports, FDA Form 483, warning letters or actions taken by any Regulatory Agencies, and any instances of serious or continuing noncompliance with regulatory requirements that relate to this clinical investigation or research, must be reported immediately to the USAMRMC ORP.

Non-compliance with these terms and conditions may result in withholding of funds and/or the termination of the award.

DoD requirements for human subjects research, including 32 CFR Part 219, DoD Instruction 3216.02, and USAMRMC ORP Human Research Protection Office submission instructions can be accessed at https://mrmc.amedd.army.mil/index.cfm?pageid=research_protections.hrpo.

20.16. Prohibition of Use of Laboratory Animals

Notwithstanding any other terms and conditions contained in this Agreement or incorporated by reference herein, Research Project Awardees (or lower tier subawards) are expressly forbidden to use laboratory animals in any manner whatsoever without the express written approval of the USAMRMC, Animal Care and Use Review Office (ACURO). Written authorization to begin research under the applicable protocol(s) proposed for Research Project Award(s) will be issued in the form of an approval letter from the USAMRMC ACURO. Furthermore, modifications to already approved protocols require approval by ACURO to the Research Project Awardee(s), a copy of which shall be provided to the appointed SOTR.

Furthermore, modifications to already approved protocols require approval by ACURO prior to implementation. For each fiscal year, a Research Project Awardee must maintain, and upon request from ACURO, submit animal usage information.

Non-compliance with any of these terms and conditions may result in withholding of funds and/or the termination of the Research Project Award.

The Animal Care and Use Office requirements can be accessed at https://mrmc.amedd.army.mil/index.cfm?pageid=research_protections.acuro.

20.17. Principal Investigator.

Each Research Project Award shall identify a Principal Investigator. This individual shall be continuously responsible for the conduct of the research project. The Research Project Awardee, through the CM, shall obtain the AO's approval to change the Principal Investigator or to continue the research work during a continuous period in excess of three months without the participation of an approved Principal Investigator. Each Research Project Award is based upon the Principal Investigator devoting a defined percentage of effort to the project over the term of the Research Project Award. The Research Project Awardee shall advise the AO if the Principal Investigator will, or plans to, revise the level of effort estimated in the Research Project Proposal. A curriculum vitae shall be provided for professional associates added to the research project or substituted during the course of work.

20.18. Notices. Any notice or other communication required or permitted under this Agreement shall be in writing and (a) personally delivered, (b) mailed, postage prepaid, first class, certified mail, return receipt requested, (c) sent, shipping prepaid, return receipt requested by national overnight courier service, or (d) sent by electronic mail to the appropriate Party or Parties at the addresses as set forth herein, or at such other addresses as may be given from time to time in accordance with the terms of this notice provision. Any notice or other communication given by personal delivery or electronic mail shall be deemed given on the date personally or electronically delivered; any notice or other communication given by mail shall be deemed given five (5) calendar days after the date deposited in the United States mail; and any notice or other communication given by national overnight courier service shall be deemed given on the next business day after being sent.

For the CM:

See Section 7.2.1

For the Base Agreement Awardee:

See Section 7.2.1

20.19. Waiver. No waiver of any rights shall be effective unless assented to in writing by the Party to be charged, and the waiver of any breach or default shall not constitute a waiver of any other right hereunder or any subsequent breach or default.

20.20. Security. Work under Research Projects Awards may involve access to information classified as "Confidential," "Secret," or "Top Secret." If it is determined that access to

classified information will be required during the performance of a Research Project Award, a Department of Defense (DD) Form 254 will be attached to the Agreement; and term similar to FAR 52.204-2 – Security Requirements will be incorporated. The Research Project Awardee and its employees who work on such Research Projects shall comply with (a) the Security Agreement (DD Form 441), including the National Industrial Security Program Operation Manual (DoD 5220.22-M) and (b) any revisions to that manual that may be issued of security documents or procedures appropriate for other Government agencies. During the course of this Agreement, the Parties may determine that information developed by the Research Project Awardee, and/or the Government pursuant to this Agreement shall be treated as classified. Such information shall be classified in accordance with DoD 5220.22-M or other appropriate non DoD requirements.

20.21. 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.

20.22. 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 severability shall be effective if the result of such action materially changes the economic benefit of this Agreement to the Parties.

20.23. 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.

20.24. Public Announcements. Any written announcements, press releases, or similar publicity (collectively, “Announcements”) with respect to the execution of this Agreement shall be agreed upon by the CM, the Government, and the affected Consortium Member in advance of such Announcement. Each party agrees to provide to the other party a copy of any proposed public Announcements relating to this Agreement as soon as reasonably practicable under the circumstances prior to its scheduled release. Each party shall have the right to expeditiously review and recommend changes to any Announcement regarding this Agreement. Except as otherwise required by law, the party whose Announcement has been reviewed shall consider in good faith the removal of any information any reviewing party reasonably deems to be inappropriate for disclosure. In proposing, reviewing, and considering comments on Announcements, the interests of the all parties shall be taken into consideration, with the overall goal being the furtherance of the objectives of this Agreement and the harmonization of the interests of all parties. Public release of information related to this Agreement and individual Research Project Awards will follow the procedure set forth in Article 12– Publication and Academic Rights. Nothing

herein will prohibit or constrain the Government from exercising its statutory and regulatory requirements to the full extent thereof.

20.25. Force Majeure. No failure or omission by the CM or Base Agreement Awardee 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 the control of the Parties, including, but not limited to, the following: acts of God; acts or omissions of any Government; any rules, regulations or orders issued by any Government 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.

20.26. Order of Precedence. In the event of any inconsistency between the terms of this Agreement and the terms of any Research Project Award made pursuant to this Agreement, the inconsistency shall be resolved by giving precedence in the following order: (1) the Research Project Award and the applicable Statements of Work, drawings, and specifications, including but not limited to the Project Approval Letter and the Research Project Proposal selected for funding by the Government and (2) this Base Agreement.

20.27. Excluded Statutes. The Parties understand and agree that this Agreement as well as any Research Project Awards awarded pursuant to this Agreement ARE NOT subject to the Competition in Contracting Act, the Contract Disputes Act, and the GAO Procurement Protest System.

20.28. Code of Conduct. No employee, officer, or agent of any party to this Agreement shall participate in the selection, award, or administration of a contract supported by Federal funds if a real or apparent conflict of interest would be involved. Such a conflict would arise when the employee, officer, or agent, any member of his or her immediate family, his or her partner, or an organization which employs or is about to employ any of the parties indicated herein, has a financial or other interest in the firm selected for an award. The officers, employees, and agents of the recipient shall neither solicit nor accept gratuities, favors, or anything of monetary value from contractors, or parties to subagreements. However, recipients may set standards for situations in which the financial interest is not substantial or the gift is an unsolicited item of nominal value. The standards of conduct shall provide for disciplinary actions to be applied for violations of such standards by officers, employees, or agents of the recipient.

20.29. Follow-On Production Provision. In accordance with 10.U.S.C. 2371b(f), and upon a determination that any competitively awarded prototype project has been successfully completed, the prototype project may result in the award of a follow-on production contract or transaction without the use of competitive procedures.

20.30. Flow down. The Base Agreement Awardee shall include Articles 20.2, 20.7, 20.9, 20.11, 20.12, 20.13, 20.14, 20.15, 20.16, 20.20, 20.24, and 20.28, suitably modified to identify all parties, in all subawards. These Articles shall, in turn, be included in all sub-tier subawards or other forms of lower tier agreements, regardless of tier. The government will be a third party in interest for purposes of these Articles in any agreement where flow-down of rights and obligations is required.

ARTICLE 21. REFERENCES

For reference only and **NOT** incorporated into this Agreement.

1. DoD Directive 7045-14
2. AR 40-32, The Care and Use of Laboratory Animals in DoD Programs
3. DoD Instruction 3216.01, Use of Animals in DoD Programs
4. Title 32 Code of Federal Regulations Part 219, Protection of Human Subjects
5. 21CFR Parts 50 and 56, Institutional Review Board, Part 312, Investigation of New Drug Applications, Part 812, Investigational Device Exemption
6. 45 CFR 160-164, Public Welfare
7. DoD Directive 3216.02, Protection of Human Subjects and Adherence to Ethical Standards in DoD Supported Research
8. AR 70-25, Use of Volunteers as Subjects of Research