

Request for Project Proposals



Solicitation Number: MTEC-20-07-Qual-Regen
“Quality Assurance for Biomanufactured Regenerative Medicine Products (Qual-Regen)”

Issued by:
Advanced Technology International (ATI),
MTEC Consortium Manager (CM)
315 Sigma Drive
Summerville, SC 29486
for the
Medical Technology Enterprise Consortium (MTEC)

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White Papers Are NOT Required

Table of Contents

1	Executive Summary	3
1.1.	The Medical Technology Enterprise Consortium	3
1.2.	Purpose	3
2	Administrative Overview	5
2.1.	Request for Project Proposals (RPP)	5
2.2.	Proposers Conference	5
2.3.	Funding Availability, Period of Performance, and Type of Funding Instrument Issued	5
2.4.	Acquisition Approach	5
2.5.	MTEC Member Teaming	6
2.6.	Proprietary Information	7
2.7.	Offeror Eligibility	7
2.8.	Inclusion of Nontraditional Defense Contractors, Nonprofit Research Institutions, or Small Business Participation	7
2.9.	Nontraditional Defense Contractor Definition	8
2.10.	Cost Sharing Definition	8
2.11.	MTEC Assessment Fee	10
2.12.	Intellectual Property & Data Rights	10
2.13.	Expected Award Date	11
2.14.	Anticipated Solutions Brief Selection Notification	11
3	Solution Brief	11
3.1.	Solution Brief Rationale	11
3.2.	Solution Brief Submission	11
3.3.	Submission Format	11
4	Solution Brief Preparation Instructions	12
4.1.	General Instructions	12
5	Technical Requirements	12
	Overall Objective of RPP:	13
	Technical Objectives of RPP:	13
6	Solution Brief Preparation	15
6.1.	Preparation of the Solution Brief	15
6.2.	Cost Proposal	22
6.3.	Freedom of Information Act (FOIA)	22
6.4.	Solution Brief and Cost Proposal Preparation Costs	22
7	Selection	22
8	Points-of-Contact	23
9	Acronyms/Abbreviations	24
	Attachment A: Statement of Work (SOW)	26
	Attachment B: Solution Brief Budget Summary Form	29
	Attachment C: Biosketches	32
	Attachment D: Data Rights	34
	Attachment E: Quad Chart Template	35
	Attachment F: Current and Pending Support	36

1 Executive Summary

1.1. The Medical Technology Enterprise Consortium

The Medical Technology Enterprise Consortium (MTEC) is an enterprise partnership in collaboration with industry and academia to facilitate research and development activities, in cooperation with the U.S. Army Medical Research and Development Command (USAMRDC) and other DoD agencies in the biomedical sciences (including but not limited to drugs, biologics, vaccines, medical software and medical devices) to protect, treat and optimize the health and performance of U.S. military personnel. MTEC is a nonprofit corporation with the following principal objectives:

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

*Note: Pending successful completion of this effort, the Government may issue a non-competitive follow-on production contract or transaction pursuant to 10 USC 2371b section f.

MTEC is openly recruiting members to join a broad and diverse biomedical consortium that includes representatives from large businesses, small businesses, contract research organizations, “nontraditional” DoD contractors, academic research institutions and not-for-profit organizations; for more information on the MTEC mission, see the Proposal Preparation Guide (PPG) and MTEC website.

MTEC operates under an Other Transaction Agreement (OTA) for prototype projects with USAMRDC. Proposed prototype projects should not be exploratory in nature and do require a foundation of preliminary data. As defined in the OTA Guide dated November 2018, a prototype project addresses a proof of concept, model, reverse engineering to address obsolescence, pilot, novel application of commercial technologies for defense purposes, agile development activity, creation, design, development, demonstration of technical or operational utility, or combinations of the foregoing. A process, including a business process, may be the subject of a prototype project. Although assistance terms are generally not appropriate in OT agreements, ancillary work efforts that are necessary for completion of the prototype project, such as test site training or limited logistics support, may be included in prototype projects. A prototype may be physical, virtual, or conceptual in nature. A prototype project may be fully funded by DoD, jointly funded by multiple federal agencies, cost-shared, funded in whole or part by third parties, or involve a mutual commitment of resources other than an exchange of funds.

1.2. Purpose

This solicitation, issued by the MTEC Consortium Manager (CM), Advanced Technology International (ATI), represents a Request for Project Proposals (RPP) for MTEC support of the USAMRDC Clinical and Rehabilitative Medicine Research Program (CRM RP). Military relevance is a critical component of Solution Brief submission. Strategic and tactical oversight for the award(s) supported by this RPP will be provided by the Joint Program Committee 8 (JPC-8)/CRM RP.

Applications for this RPP are being solicited for the Defense Health Agency, J-9 Research and Development (DHA R&D) Directorate. As directed by the Office of the Assistant Secretary of Defense for Health Affairs (OASD[HA]), the DHA J-9 R&D Directorate manages the Defense Health Program (DHP) Research, Development, Test, and Evaluation (RDT&E) appropriation for which funds are being made available to advance the state-of-the-art in biomedical manufacturing.

The JPC-8/CRM RP, DHA RDA, and OASD(HA) have identified a need for regenerative medicine prototype development efforts and manufacturing technologies. Current Good Manufacturing Practice (cGMP) quality is a requirement by the Food and Drug Administration (FDA) and European Medicines Agency to provide patients with clinical-grade products that are safe and have defined quality characteristics. However, process standardization and robust manufacturing techniques are lacking in regenerative medicine, which will continue to impede progress in advancing regenerative medicine based technologies and treatments toward the clinic. This is likely due to the immaturity of the regenerative medicine field, which could benefit from the development and advancement of many manufacturing capabilities.

This RPP focuses on quality management of biomanufacturing processes and/or development of a prototype for a universal biomanufactured product or process. Applications should clearly state innovative solutions for the biomanufacturing of regenerative medicine products and regulatory strategies to obtain FDA clearances or approvals, if appropriate. This RPP offers the opportunity for industry funding to join the project as it leads to stronger leveraging of Government-contractor collaboration. While not a requirement, Offerors are strongly encouraged to include Cost Share as appropriate.

The major objective of this RPP is to overcome current challenges in biomanufacturing of regenerative medicine products and enable successful cGMP manufacturing and clinical translation of regenerative medicine based therapies. To accomplish this we are seeking solutions for quality management of manufacturing processes or prototypes for cell, tissue, or organ bioengineering technologies. **This RPP specifically targets solutions to the following Focus Areas (see Section 5 for more details):**

- 1) Processing technologies for quality management of acellular matrices or Stem Cell (SC)-derived cell based therapies**
- 2) Manufactured universal acellular matrix**
- 3) Innovative manufacturing process for SC-derived cell based therapies**

To meet the intent of this RPP, proposed prototype solutions must address at least one of the three Focus Areas listed above.

2 Administrative Overview

2.1. Request for Project Proposals (RPP)

MTEC recognizes that considerable effort is required to prepare a competitive proposal to MTEC. Therefore, this RPP will be conducted using a multi-step approach. In Step 1, current MTEC members are invited to submit Solution Briefs. Each MTEC Solution Brief submitted shall be in accordance with the mandatory format provided in the MTEC PPG, which is available on the Members-Only MTEC website at www.mtec-sc.org. ***White papers are not required for this RPP.*** The Government reserves the right to award prototype projects based on Step 1 Solution Briefs received from this RPP.

2.2. Proposers Conference

MTEC will host a Proposers Conference within 2 weeks after the release of the RPP that will be conducted via webinar. Further instructions will be forthcoming via email. Offerors are advised to check the MTEC website periodically during the Solution Brief preparation period for any clarifications found in Frequently Asked Questions (FAQ) responses.

2.3. Funding Availability, Period of Performance, and Type of Funding Instrument Issued

The U.S. Government (USG) Department of Defense (DoD) currently has available approximately \$16.9 Million (M) of Fiscal Year (FY) 2019 and 2020 to fund approximately 6 projects (up to \$2.82M/project) for 3 years. Awards resulting from this RPP are expected to be made in FY20, subject to available federal funds for this program. The DoD may apply additional dollars for follow-on efforts via post award modification to any resultant awards after the evaluation and acceptance of work and cost plan.

The anticipated Period of Performance (PoP) for each focus area is 3 years. Dependent on the results and deliverables, additional time may be added to the period of performance for follow-on tasks.

As of the release date of this RPP, future year Defense Appropriations Bills have not been passed and there is no guarantee that any additional funds will be made available to support this program. The funding estimated for this RPP is approximate and subject to realignment. The Government anticipates that award funding will be structured incrementally and based upon completion of Milestones and Deliverables.

2.4. Acquisition Approach

It is expected that **MTEC will make a total of 6 awards (up to \$2.82M/award)** to qualified teams to accomplish the statement of work. If a single proposal is unable to sufficiently address the entire scope of a specific focus area (outlined in Section 5), several Offerors may be asked to work together in a collaborative manner. However, if an optimal team is not identified, then MTEC may make multiple, individual awards to Offeror(s) to accomplish subset(s) of the key tasks.

The Government-selected Awards will be funded under the Other Transaction Agreement for prototype projects (OTA) Number W81XWH-15-9-0001 with MTEC administered by the CM, ATI. The CM will negotiate and execute a Base Agreement with MTEC members (if not yet executed). This Base Agreement will be governed by the same provisions as the OTA between the DoD and MTEC. Subsequently, any Solution Brief that is selected for award will be funded through a Research Project Award issued under the member's Base Agreement. A sample of the MTEC Base Agreement can be found on the MTEC Members-Only website at www.mtec-sc.org.

At the time of the submission, if Offerors have not yet executed a Base Agreement, then Offerors must certify on the cover page of their Solution Brief that, if selected for award, they will abide by the terms and conditions of the latest version of the MTEC Base Agreement. If the Offeror already has executed an MTEC Base Agreement with the MTEC CM, then the Offeror must state on the cover page of its Solution Brief that, if selected for award, it anticipates the proposed effort will be funded under its executed MTEC Base Agreement.

Offerors are advised to check the MTEC website periodically during the Solution Brief preparation period for any changes to the MTEC Base Agreement terms and conditions.

2.5. MTEC Member Teaming

While teaming is not required for this effort, Offerors are encouraged to consider teaming during the proposal preparation period (prior to proposal submission) if they cannot address the full scope of technical requirements of the RPP or otherwise believe a team may be beneficial to the Government.

MTEC members are encouraged to use the MTEC Database Collaboration Tool. The purpose of the tool is to help MTEC member organizations identify potential teaming partners by providing a quick and easy way to search the membership for specific technology capabilities, collaboration interest, core business areas/focus, R&D highlights/projects, and technical expertise. The Primary Point of Contact for each member organization is provided access to the collaboration database tool to make edits and populate their organization's profile. There are two sections as part of the profile relevant to teaming:

- "Collaboration Interests" - Select the type of teaming opportunities your organization would be interested in. This information is crucial when organizations need to search the membership for specific capabilities/expertise that other members are willing to offer.
- "Solicitation Collaboration Interests" - Input specific active solicitations that you are interested in teaming on. This information will help organizations interested in a specific

funding opportunities identify others that are interested to partner in regards to the same funding opportunity. Contact information for each organization is provided as part of the member profile in the collaboration database tool to foster follow-up conversations between members as needed.

The Collaboration Database can be accessed via the “MTEC Profiles Site” tab on the MTEC members-only website.

2.6. Proprietary Information

The MTEC CM will oversee submission of Proposals submitted in response to this RPP. The MTEC CM shall take the necessary steps to protect all proprietary information and shall not use such proprietary information for purposes other than the evaluation of an Offeror’s Proposal and the subsequent agreement administration if the Proposal is selected for award. In accordance with the PPG, please mark all Confidential or Proprietary Information as such. An Offeror’s submission of a Proposal under this RPP indicates concurrence with the aforementioned CM responsibilities.

Also, as part of MTEC’s mission to incorporate philanthropic donations, MTEC frequently makes contact with private entities (e.g., foundations, investor groups, organizations, individuals) that award grants or otherwise co-fund research, and/or operates in research areas that are aligned with those of MTEC. These private entities may be interested in reviewing certain Proposals within their program areas, allowing opportunities to attract supplemental funding sources. On your Proposal Cover Page, please indicate your willingness to allow MTEC Officers and Directors access to your Proposal for the purposes of engaging in outreach activities with these private organizations. MTEC Officers and Directors granted Proposal access have signed Non-disclosure Agreements (NDAs) and Organizational Conflict of Interest (OCI) statements. Additionally, these MTEC Officers and Staff represent organizations that currently are not MTEC members, and therefore their parent organizations are not eligible to submit Proposals or receive any research project funding through MTEC. Additionally, all Technical Evaluation Panel participants will agree to, and sign a nonproprietary information and conflict of interest document.

2.7. Offeror Eligibility

Offerors must be MTEC Members in good standing. Offerors submitting Solution Briefs as the prime contractor must be MTEC members of good standing by **April 9, 2020**.

2.8. Inclusion of Nontraditional Defense Contractors, Nonprofit Research Institutions, or Small Business Participation

Proposals that fail to meet the mandatory statutory conditions with regard to the appropriate use of Other Transaction Authority, as listed below, will not be evaluated and will determined ineligible for award. Please see the MTEC PPG and RPP (Section 5) for additional details.

Mandatory statutory conditions (the Offeror shall assert that at least one of the one of the following conditions is met):

(1) There is at least one nontraditional defense contractor or nonprofit research institution participating to a significant extent in the prototype project.

(2) All significant participants in the transaction other than the Federal Government are small businesses (including small businesses participating in a program described under section 9 of the Small Business Act (15 U.S.C. 638)) or nontraditional defense contractors.

(3) At least one third of the total cost of the prototype project is to be paid out of funds provided by sources other than the Federal Government.

The Offeror shall submit Warranties and Representations (see Attachment 2 of the PPG) specifying the critical technologies being offered and/or the significant extent of participation of the nontraditional defense contractor, small business or nonprofit research institution. The nontraditional defense contractor can be an individual so long as he/she has a DUNS Number and meets the requirements in the Warranties and Representations. The significance of the nontraditional defense contractor's, small business' or nonprofit research institution's participation shall be explained in detail in the signed Warranties and Representations. Inadequate detail can cause delay in award.

Per the DoD OT Guide, rationale to justify a *significant extent* includes:

1. Supplying a new key technology, product or process
2. Supplying a novel application or approach to an existing technology, product or process
3. Providing a material increase in the performance, efficiency, quality or versatility of a key technology, product or process
4. Accomplishing a significant amount of the prototype project
5. Causing a material reduction in the cost or schedule of the prototype project
6. Provide for a material increase in performance of the prototype project

2.9. Nontraditional Defense Contractor Definition

A nontraditional defense contractor is a business unit that has not, for a period of **at least one year prior to the issue date of the Request for Project Proposals**, entered into or performed on any contract or subcontract that is subject to full coverage under the cost accounting standards (CAS) prescribed pursuant to section 26 of the Office of Federal Procurement Policy Act (41 U.S.C. 422) and the regulations implementing such section.

2.10. Cost Sharing Definition

Cost sharing is defined as the resources expended by the award recipients on the proposed statement of work (SOW). If cost sharing is proposed, then the Offeror shall state the amount that is being proposed and whether the cost sharing is a cash contribution or in-kind contribution (see below for a definition of each); provide a description of each cost share item proposed; the proposed dollar amount for each cost share item proposed; and the valuation technique used (e.g., vendor quote, historical cost, labor hours and labor rates, number of trips, etc.). Cost sharing is encouraged if possible, as it leads to stronger leveraging of Government-contractor collaboration.

Cash Contribution

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.

An Offeror'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 Offeror 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 Offeror's cash.

Cash contributions include the funds the Offeror 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.

In-Kind Contribution

In Kind Contribution means the Offeror's 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.

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.

See the MTEC PPG for additional details. If the offer contains multiple team members, this information shall be provided for each team member providing cost share.

2.11. MTEC Assessment Fee

Per Section 3.4 of the Consortium Member Agreement (CMA), each recipient of a Research Project Award under the MTEC OTA shall pay MTEC an amount equal to 1% of the total funded value of each research project award. Such deposits shall be due no later than 90 days after the research project award is executed. Awardees are not allowed to use MTEC funding to pay for their assessment fees.

Additionally, MTEC has established two methods of payment to be made to MTEC surrounding the licensing/commercialization of Intellectual Property developed with funding received from MTEC Research Project Awards:

Royalty Payment Agreements

Government-funded research projects awarded through MTEC will be subject to a 10% royalty on all Net Revenues received by the Research Project Award recipient resulting from the licensing/commercialization of the technology, capped at 200% of the Government funding provided.

Additional Research Project Award Assessment

In lieu of providing the royalty payment agreement described above, members receiving Research Project Awards may elect to pay an additional assessment of 2% above the standard assessment percentage described in Section 3.4 of the CMA. This additional assessment applies to all research project awards, whether the award is Government funded or privately funded.

2.12. Intellectual Property & Data Rights

Potential offerors should be aware that the Government intends to specially negotiate the rights in intellectual property (IP) and technical data developed under this agreement and negotiate FDA sponsorship and other regulatory rights on a case-by-case basis. Accordingly, for this acquisition, the government seeks: Government Purpose Rights or Unlimited Rights. These specially negotiated rights may differ from the base MTEC terms.

MTEC reserves the right to assist in the negotiation of IP, royalties, licensing, future development, etc., between the government and the individual performers during the entire award period.

The Offeror shall comply with the terms and conditions defined in the Base Agreement regarding Data Rights. **It is anticipated that anything delivered under this proposed effort would be delivered to the Government with Government purpose data rights or unlimited data rights unless otherwise asserted in the proposal and agreed to by the Government.** Rights in technical data in each Research Project Award shall be determined in accordance with the provisions of MTEC Base Agreement.

The Offeror is required to complete Attachment D (Data Rights) of the RPP in its Step 1 Solution Brief submission to identify any items to be furnished to the Government with restrictions.

2.13. Expected Award Date

Offeror should plan on the period of performance beginning September 30, 2020 (subject to change). The Government reserves the right to change the proposed period of performance start date through negotiations via the CM and prior to issuing a Research Project Award.

2.14. Anticipated Solutions Brief Selection Notification

As the basis of selections is completed, the DoD will forward their selections to MTEC CM to notify Offerors. Proposers will be notified by letter from the MTEC of the results of the evaluation. Those favorably evaluated (receive an overall rating of “good” or higher) will move forward to the next phase of solution brief pitch while those who are not favorably evaluated will gain evaluation rationale for non-selection.

3 Solution Brief

3.1. Solution Brief Rationale

The MTEC will use a streamlined, interactive approach for this RPP. Because of the nature of the requirements set forth in this RPP, this streamlined, interactive approach is anticipated to be a better means to highlight company methodologies and skills that should allow the Government to gain a fuller appreciation of the work required to be completed. It provides more freedom and initiative to the Offeror to describe how the Offeror would approach and solve such an action. The following sections describe the formats and requirements of the Solution Brief.

Offerors who submit Solution Briefs in response to this RPP must submit by the date on the cover page of this RPP. Solution Briefs received after the time and date specified will not be evaluated.

3.2. Solution Brief Submission

Solution Briefs shall be submitted by the date and time specified on the cover page using BIDS: <https://ati2.acqcenter.com/ATI2/Portal.nsf/Start?ReadForm>. Include the MTEC Solicitation Number (MTEC-20-07-Qual-Regen) on each Solution Brief submitted.

Do not submit any classified information in the Solution Brief submission.

3.3. Submission Format

Offerors shall submit files in Microsoft Office formats or Adobe Acrobat (PDF – portable document format) as indicated below. ZIP files and other application formats are not acceptable. All files must be print-capable and without a password required. Filenames must contain the appropriate filename extension (.docx, .doc, .pptx, .ppt, .xlsx, .xls or .pdf). Filenames should not contain special characters. Apple users must ensure the entire filename and path are free of spaces and special characters.

An automated BIDS receipt confirmation will be provided by email.. Offerors may submit in advance of the deadline and update (or replace any of the files) up until the submission deadline. **Neither MTEC nor ATI will make allowances/exceptions for submission problems encountered by the Offeror using system-to-system interfaces. If the Offeror receives errors and fails to upload the full submission prior to the submission deadline, the submission will not be accepted. It is the Offeror's responsibility to ensure a timely and complete submission.**

4 Solution Brief Preparation Instructions

4.1. General Instructions

The Solution Brief and Cost Proposal format provided in this MTEC RPP are mandatory and shall reference this RPP number (MTEC-20-07-QualRegen). Offerors are encouraged to contact the Point-of-Contact (POC) identified herein up until the Solution Brief submission date/time to clarify requirements.

All eligible Offerors may submit Solution Briefs for evaluation according to the criteria set forth herein. Offerors are advised that only ATI as the MTEC's CM, with the approval of the DoD Agreements Officer, is legally authorized to contractually bind or otherwise commit funding for selected Awards as result of this RPP.

5 Technical Requirements

The mission of the JPC-8/CRM RP is to implement long-term strategies to develop knowledge and materiel products to reconstruct, rehabilitate, and provide definitive care for injured Service Members. The ultimate goal is to return the Service Member to duty and restore their quality of life. Military relevance is a critical component of proposal submission. Innovations developed from CRM RP-supported research efforts are expected to improve restorative treatments and rehabilitative care to maximize function for return to duty (RTD) or civilian life. The CRM RP interest is in medical technologies (drugs, biologics, and devices) and treatment/rehabilitation strategies (methods, guidelines, standards, and information) that will significantly improve the medical care provided to our wounded Service Members within the DoD health care system. Implementation of these technologies and strategies should improve: the rate of RTD of Service members, the time to RTD, limited duty days, loss of duty days, clinical outcome measures, quality of life, as well as reduce the hospital stay lengths, clinical workload (patient encounters, treatments, etc.), and initial and long-term costs associated with restorative and rehabilitative or acute care. The CRM RP focuses its efforts on the following research areas: neuromusculoskeletal injury (including amputees), sensory systems (including hearing, balance, tinnitus, and vision), acute and chronic pain, and regenerative medicine.

Problem Definition:

There is a lack of available regenerative medicine products to treat traumatic injuries and restore function. There is a need to advance the field of biomanufacturing in parallel to product development of regenerative medicine interventions and clinical treatments.

Overall Objective of RPP:

The major objective of this solicitation is to develop solutions for quality management of prototypes and processes for cell, tissue, or organ bioengineering technologies that will overcome current challenges in biomanufacturing of regenerative medicine products; and to also enable successful cGMP manufacturing and clinical translation of regenerative medicine based therapies.

In order to qualify for an award under this RPP, the proposed project must fall within the prescribed areas of military need and which has a manufacturing component necessary to continue its development. Example areas of military need are: Regenerative treatments for neuromusculoskeletal injury (e.g., functional nerve regeneration, regeneration of large volume vascularized muscle, or functional bone regeneration), skin injury, or restoration of organ function. In addition to addressing military need, projects should also address two critical objectives: 1) improving the manufacturing process; and, 2) making product available for applied research or clinical studies.

Technical Objectives of RPP:

All Solution Brief submissions should describe projects that are based on logical reasoning and sound scientific rationale. They should not be exploratory in nature and do require a foundation of preliminary data. Please note that MTEC-sponsored projects must result in “prototype” research deliverables that transition medical solutions to industry.

To meet the intent of this RPP, proposed prototype solutions **must** address **at least one** of the three Focus Areas described below. An ideal Solution Brief is one that integrates manufacturing process or quality management development with scientific testing and characterization throughout the project. Solution Briefs may address one or more focus areas. Projects not aligned to at least one of these Focus Areas will not be considered for funding. **These focus areas of interest are listed in order of importance.**

1. FOCUS AREA #1: Processing technologies for Quality Management of Acellular Matrices or SC-Derived Cell Based Therapies (Assurance or Quality Testing)

Topics of interest include but are not limited to:

- a. The majority of regenerative medicine products depend on a biological source, which can limit the quantity of manufactured product. Limited quantities of either autologous or allogeneic interventions presents a challenge to quality control and testing. Developing non-destructive testing or alternatives to batch/lot testing is necessary to increase the yield of regenerative medicine products.

- b. A challenge to implementing matrices or SC-derived cells is that they change throughout the manufacturing process and monitoring throughout the process will enable regulatory approval. Some scaffolds begin as simple structures but through additive manufacturing become complex specialized configurations. SC-derived cells may change from a pluri- or multipotent cell to a restricted or mature cell phenotype. Developing in-line real time monitoring or real time release testing will help to ensure the biomanufacturing process remains on course and is on target.

2. FOCUS AREA #2: Manufactured Universal Acellular Matrix

Topics of interest include but are not limited to:

- a. There is a diverse number of regenerative strategies that propose to use a type of matrix device to restore function after traumatic injury. The nomenclature for these devices is extensive but include scaffold, graft, conduit, and construct, and within each type, many researchers are testing different bioactive molecules to promote regeneration. Each slightly different device will have specific regulatory challenges. It would be beneficial, therefore, to develop a universal acellular matrix, or subcomponents for one, which can be manufactured to serve as a starting point or foundational device, (for acellular matrices that share common elements and can be produced to a certain step before specialization).
- b. The ability for specialization or customization to meet needs of an injured biological system is also important. It is reasonable to expect that different bioactive molecules are required for different biological systems. Therefore, it is essential to develop a universal matrix that can be tunable or specialized for specific treatments.

3. FOCUS AREA #3: Innovative Manufacturing Process for Stem Cell (SC)-Derived Cell Based Therapies

Topics of interest include but are not limited to:

- a. Many regenerative strategies in development plan to use SC-derived cells to restore structure and function after traumatic injury. Whether the cells are injected, implanted, or impregnated a common manufacturing design process could help to produce consistent homogenous or heterogenous differentiated populations of cells to be used as a source raw material.

Offerors are encouraged to consider teaming to address the technical requirements of this RPP (if one Offeror cannot address the full scope of technical requirements individually) or if teaming may otherwise be beneficial to the Government. Offerors are encouraged to bring forth Solution Briefs that include study teams with both scientific and manufacturing experience. Note that, if an optimal team is not identified or if a single Solution Brief is unable to sufficiently address the entire scope of this RPP's technical requirements, specific focus area (both scientific and manufacturing experience), several Offerors may be asked to work together in a collaborative manner. For example, the Government may request that an Offeror with manufacturing capabilities be teamed with another Offeror with quality management or scientific capabilities.

Potential Follow-on Task:

There is potential for award of one or more follow-on tasks based on the success of this project (subject to change depending upon Government review of work completed). Note that any potential follow on work is expected to be awarded non-competitively to resultant project awardees:

- Designing and implementing pilot or full-scale Good Manufacturing Practice (GMP) production of successful products for use in advanced preclinical and initial clinical trials;
- Development of prototype device to Investigational Device Exemption (IDE) stage for initiation of clinical trials;
- Pre-clinical testing in validated animal model to test safety and efficacy of manufactured product or cell based therapy for the advancement of prototype development toward regulatory filing for initiation of clinical trials;
- Conduct of clinical trials.

Restrictions on Animal and Human Subjects:

Solution Briefs must comply with restrictions and reporting requirements for the use of animal and human subjects, to include research involving the secondary use of human biospecimens and/or human data. The Awardee shall ensure local Institutional Animal Care and Use Committee (IACUC) and Institutional Review Board (IRB) approvals, continuing review (in the intervals specified by the local IACUC and IRB, but at a minimum, annually), and approval by the U.S. Army Animal Use and Review Office (ACURO) and U.S. Army Human Research Protections Office (HRPO). Offerors shall include IACUC, ACURO, IRB and HRPO review and approval in the SOW/Milestones Table submitted with the Solution Brief Pitch.

These restrictions include mandatory government review and reporting processes that will impact the Offeror's schedule.

For example, the animal studies under this RPP shall not begin until the ACURO provides authorization that the research may proceed. The USAMRDC ACURO will issue written approval to begin research under separate notification. Written approval to proceed from the USAMRDC ACURO is also required for any Research Project Awardee (or lower tier subawards) that will use funds from this award to conduct research involving animals. Offerors must allow at least 60 days in their schedule for the ACURO review and authorization process.

6 Solution Brief Preparation

6.1. Preparation of the Solution Brief

Offerors submitting Solution Briefs in response to this RPP will be required to submit using the following steps outlined below:

Step 1: Solution Brief

The Offeror shall submit a Solution Brief, which describes the overall technical concept and approach along with the viability toward the Offeror's specific effort. The following sections must be included in the Solution Brief:

- **Cover Page (1 page limit)** must include the following information:
 - Title of Solution Brief
 - Offeror's name and contact information (such as name of the organization, point of contact's name, email address, phone number, mailing address, etc.)
 - Statement that "This Solution Brief is submitted pursuant to the RPP MTEC-20-07-Qual-Regen"
 - Dates of submission and signature of official authorized to obligate the institution contractually
 - Willingness to allow MTEC Officers access to your Solution Brief for the purposes of engaging in outreach activities with private sector entities: Indicate YES or NO [As part of MTEC's mission to incorporate philanthropic donations, MTEC frequently makes contact with private sector entities (e.g., foundations, organizations, individuals) that award grants or otherwise co-fund research, and/or operate in research areas that are aligned with those of MTEC. Additional private entities may be interested in reviewing certain Solution Briefs and Cost Proposals within their program areas, allowing opportunities to attract supplemental funding sources. Please indicate your willingness to allow MTEC access to your White Paper for the purposes of engaging in outreach activities with these private sector entities. MTEC staff has signed NDAs and OCI statements.]
- **Technical Narrative** (not to exceed 10 pages) must include the following information:
 - **Technical Abstract:** [300 word limit; Briefly, describe project goals, hypothesis, study design, and deliverables.]
 - **Hypothesis:** [Clearly state the hypothesis for the project.]
 - **Specific Aims:** [Describe how the proposal aligns to at least one of the three focus areas; programmatic relevance. Clearly state the goals, objectives, and specific aims of the project.]
 - **Scientific Rationale / Preliminary Data:** [Describe the scientific rationale for the project, including a brief description of the previous studies or preliminary data that support the feasibility of proposed work.]
 - **Study Design:** [Briefly describe the experimental design, methods, and materials required to accomplish the proposed approach.]
 - **Anticipated Outcomes:** [Provide a description of the anticipated outcomes from the proposed work. List major milestones and deliverables from the proposed work.]
 - **Project Management Plan:** [The Solution Brief shall describe the overall project management plan.]

- **Regulatory and Commercialization Plan:** [Briefly describe regulatory plan, including FDA pathway and designation, strategy for obtaining FDA approvals or clearances. Briefly describe commercialization plan, including a description of the market (civilian and military) and sustainability.]
- **Statement of Work (SOW) (Attachment A template):** [Provide an outline of tasks to complete the specific aims of the proposed research project. Include project milestones, appropriate research approvals, annual in-progress reviews, and critical path items and critical decision points, during the performance period of the award. An estimated Gantt Chart to indicate the total proposed delivery schedule and major activities proposed is encouraged]
- **Budget Information (no page limit, Attachment B template):**
 - **Budget:** [An estimate of the total proposed research project cost with breakdown of all cost categories for each year, to include pay and benefits for individuals contributing toward the project, equipment purchases, supplies and materials, institutional overhead costs, purchased services, and travel. The budget and budget justification should include sufficient detail for the Government to determine whether the proposed costs are allowable, allocable, and reasonable for the proposed research.]
 - **Cost Share:** [It is anticipated that Government funds would provide incentive for industry funding to join the project. While not a requirement, Offerors are strongly encouraged to discuss the ability to bring leveraged funding/cost share to complete the project goals.]
 - **Non-traditional defense contractor, nonprofit research institution, or 1/3 cost sharing:** [Describe the plan to include significant participation of a non-traditional defense contractor, nonprofit research institution, or the ability to meet 1/3 cost sharing requirement. Refer to Sections 2.8-2.9 for more information.]
- **Experience (Attachment C template):** [Provide biosketches for all key personnel.]
- **Data Rights Assertions (no page limit, Attachment D template):** [Provide as Attachment D to Solution Brief. Reference RPP Section 2.12.]
- **Quad Chart (Attachment E template):** MTEC will make the Quad Chart template available on the Members Only Site and the MTEC website.

Solution Briefs must adhere to the following: 12 point font (or larger), Single-spaced, single-sided, 8.5 inches x 11 inches. Smaller type may be used in figures and tables, but must be clearly legible. Margins on all sides (top, bottom, left, and right) should be at least 0.5 inch. Solution Briefs **exceeding the specified page limit will not be accepted.**

Solution Brief Evaluation:

The CM will distribute all Solution Briefs to the Government for scientific and programmatic relevance evaluation. Solution Briefs will be evaluated based on the following criteria (evaluation factors are listed in descending order of importance):

- **Factor 1 - Scientific Plan:** Relevancy, thoroughness, and completeness of the proposed approach (e.g., the technical merit). This includes such factors as 1) hypothesis and objectives; 2) scientific rationale with supporting preliminary data; 3) scientific study design feasibility. The Government may consider SOW and estimated budget as an aspect of overall scientific feasibility.
- **Factor 2 - Programmatic Relevance:** Feasibility of the proposed solution and its alignment with the RPP's topic area and the program objective described in Section 5. How well the proposed methodology aligns with the specific focus area(s) and the overall intent of the announcement. The Government may consider the project management plan and experience as an aspect of overall programmatic relevance.
- **Factor 3 - Regulatory and Commercialization Plan:** Feasibility of regulatory and commercialization strategy.

Upon evaluation of the Solution Briefs, Offerors who received an overall rating of at least "Good" (based on the ratings table below) will be invited into Step 2 of the Solution Brief process. Offerors who are not invited to proceed into Step 2 will be provided feedback.

TABLE GENERAL MERIT RATING ASSESSMENTS	
RATING	DESCRIPTION
OUTSTANDING	Proposal meets requirements and indicates an exceptional approach and understanding of the requirements. Strengths far outweigh any weaknesses. Risk of unsuccessful performance is very low.
GOOD	Proposal meets requirements and indicates a thorough approach and understanding of the requirements. Proposal contains strengths which outweigh any weaknesses. Risk of unsuccessful performance is low.
ACCEPTABLE	Proposal meets requirements and indicates an adequate approach and understanding of the requirements. Strengths and weaknesses are offsetting or will have little or no impact on contract performance. Risk of unsuccessful performance is no worse than moderate.
MARGINAL	Proposal does not clearly meet requirements and has not demonstrated an adequate approach and understanding of the requirements. The proposal

	has one or more weaknesses which are not offset by strengths. Risk of unsuccessful performance is high.
UNACCEPTABLE	Proposal does not meet requirements and contains one or more deficiencies. Proposal is not awardable.

Step 2: Solution Brief Pitch:

In Step 2, the Offeror(s) shall provide a virtual or in-person “pitch” of the proposed project during a meeting with the Government sponsors for the research. The pitch should provide more details about the technical and business viability of the proposed work outlined in Step 1 (Solution Brief). Specifically, the pitch shall include the following:

Section 1: Feasibility

- **Approach:** The Offeror shall describe the innovative and novel approach used to deliver solution and emphasize why this approach is expected to result in a successful outcome. The Solution Brief Pitch must present summarized costs and schedule at the task level.
- **Effectiveness (Opportunity and Risk):** The Offeror will identify, assess, evaluate and clearly convey items (for known-knowns; known-unknowns and potential unknown-unknowns) for opportunities (e.g., reduction in cost or schedule, and/or improvement in performance) and risks within each appropriate project Cost, Schedule, Performance measure of effectiveness. The Offeror will identify objective measures and metrics used to assess each item, the triggering event(s), the expected result of Opportunities and Risk (if risk is unmitigated) item, and the mitigation plan for each identified risk item.
- **Current & Pending Support (no page limit) – See Attachment F:** The Offeror shall provide a list of all current and pending support.
 - For all current and pending research support (to include government and non-government), include the award number and title, funding agency and requiring activity’s names, period of performance (dates of funding), level of funding (total direct costs only), brief description of the project’s goals, and list of specific aims. If applicable, identify where the proposed project overlaps with other existing and pending research projects. Clearly state if there is no overlap.
 - If there is no current and/or pending support, enter “None.”

Section 2: Proposed Solution

- **Outcomes:** The Offeror shall provide a robust description of the proposed deliverables to include major milestones to accomplish final process or product.
- **Impact:** The Offeror shall illustrate the significance and impact of the proposed solution to include how it will enhance the DoD mission described in the RPP, and describe relevant patient populations or traumatic injuries the solution addresses.

- **Technical Progress:** The Offeror shall describe the milestones provided with objective, quantifiable, and measurable metrics that will be used to measure progress during the period of performance/delivery schedule and describe the oversight managerial methods that will be employed to maintain a quality and timely performance.
- **Data Rights Assertions:** - If applicable, please provide any updates to the data rights asserted with the Step 1 Solution Brief submission.

Section 3: Project Management

- **Relevant Experience:** The Offeror shall convey details related to key personnel and past performance(s) that demonstrate relevance to the scope of the proposed work and build confidence in the team's capabilities. They shall describe how experience of key personnel and associated subject matter experts support program's objective and requirements. Offerors should indicate how much of this relevant experience and past effort they will leverage for the proposed effort.
- **Project Management:** Detailed description of management plan and collaboration between manufacturers and scientists, to include responsibilities of each collaborator/subcontractor by task and coordination between groups.
- **Organization / Team Composition:** Strength of the organization/team proposed to complete the work and its financial stability to potentially continue the maturation of the system beyond the scope of this RPP.

Section 4: Cost Proposal

Offerors shall submit a Cost Proposal as part of its Stage 2 Solution Brief Pitch and are encouraged to contact the MTEC and/or Government with any questions so that all aspects are clearly understood by both parties. The cost proposal should include the following and be completed in accordance with the PPG.

- **Cost Proposal submission:** one Word (.docx or .doc) or PDF file for Section I: Cost Proposal Narrative (Appendix B) required. Separately, Section II: Cost Proposal Formats (by Task) either in Excel (.xlsx or .xls) or PDF format is required.
- **Warranties and Representations:** If Nontraditional Defense Contractor participation is proposed, Warranties and Representations are required. One Word (.docx or .doc) or PDF file that contains all Warranties and Representations is required.
- **Royalty or Additional Research Project Award Assessment:** Each Offeror will select either the MTEC Additional Assessment Fee or the Royalty Agreement (available on the MTEC members only website), **not both**, and submit a signed copy with the proposal.

Section 5 - Revised Statement of Work and Milestone Payment Schedule submission

One Word (.docx or .doc) or PDF file. Separately, a Word (.docx or .doc) version of the SOW and MPS and a Word (.docx or .doc) are required. Although this was submitted in Step 1 (Solution Brief), this allows the Offeror to make any required revisions and resubmit with Step 2 (Pitch) **(Attachment A template)**

If desired, the Government can request additional information related to specific areas of interest to be included in the pitch. The request for such information will be provided at the end of Step 1 and at the time of invitation to advance into Step 2.

The information discussed during the pitch provides a means for the Government to engage in a discussion with the Offeror to gain a greater understanding of the Solution Brief and the Offeror's capabilities. The pitch should be restricted to **a maximum of 1 hour** with a total time of 2 hours to include questions from the Government and discussion. Any materials that will be presented during the pitch or included as supplementary material must be provided at least 72 hours prior to the meeting date. If an in-person meeting cannot be accommodated by the Offeror, then a minimum of a telephonic discussion accompanied by written support material will be required. Briefing slides or documents or a combination thereof can be used to support this effort.

Evaluation of Step 2: The Government will evaluate the information provided in each Offeror's Solution Brief (Step 1) and the Solution Brief Pitch (Step 2) to determine which pitch(es) provide(s) the greatest value to the Government. Such a determination will be based on the following criteria (of equal importance):

- 1) **Factor 1 - Feasibility:** The Government will evaluate the overall approach and proposed outcomes for the degree to which the Offeror demonstrates a proposed solution that addresses objectives described in this RPP, to include proposed technical progress, schedule, and cost and the overall likelihood of success. The Government may consider innovativeness and novelty of approach, current/pending support, or effectiveness (opportunity and risk) and its impact on the overall project feasibility.
- 2) **Factor 2 - Proposed Solution:** Proposed deliverables and milestones. How well the proposed solution addresses objectives described in this RPP to include outcomes, impact, and metrics for technical progress (how it will enhance the DoD mission and relevant patient populations or traumatic injuries) The Government may consider data rights assertions as an aspect of the proposed solution.
- 3) **Factor 3 - Project Management:** The Government will evaluate the Offeror's team composition to the degree to which it demonstrates appropriate expertise and relevant experience. The Government will also consider the feasibility of SOW and timeline to deliver milestones and accomplish tasks on time. If teaming is proposed, the Government will evaluate the Offeror's plan detailing the responsibilities of each collaborator/subcontractor by task and coordination between groups.

At the conclusion of the Step 2 evaluation, Offerors who are favorably evaluated (receive an overall rating of at least "Good") will be invited to submit a final solution brief (which may be

amended from the initial brief to incorporate discussion points from the government interaction) and a cost proposal.

6.2. Cost Proposal

will make the cost proposal formats available on the Members-Only MTEC website. Refer to the MTEC PPG for additional details. Please be aware that full Cost Proposals shall be submitted as part of the Stage 2 Solution Brief Submission.

Each cost should include direct costs and other necessary components as applicable, for example, fringe, General & Administrative Expense (G&A), Facilities & Administrative (F&A), Other Direct Costs (ODC), etc. Offerors shall provide a breakdown of material and ODC costs as applicable.

6.3. Freedom of Information Act (FOIA)

To request protection from FOIA disclosure as allowed by 10 U.S.C. §2371(i), Offerors shall mark business plans and technical information with a legend identifying the documents as being submitted on a confidential basis. For more information, please refer to Section 6.1.1 of the MTEC PPG.

6.4. Solution Brief and Cost Proposal Preparation Costs

The cost of preparing Solution Briefs and Cost Proposals in response to this RPP is not considered a direct charge to any resulting award or any other contract.

7 Selection

The CM will conduct a preliminary screening of submitted Solution Briefs (Step 1) to ensure compliance with the RPP requirements. Solution Briefs that do not meet these requirements may be eliminated from the competition or additional information may be requested. One of the primary reasons for non-compliance or elimination during the initial screening is the lack of significant nontraditional defense contractor participation, nonprofit research institution participation, or cost share (see RPP Section 2.8. The Cost Sharing/Nontraditional Contractor determination will be made as shown in Table 1:

TABLE - COST SHARING/NONTRADITIONAL CONTRACTOR ASSESSMENTS	
RATING	DESCRIPTION
PASS	Offeror proposing an MTEC research project meets at least ONE of the following: <ul style="list-style-type: none">• Offeror is a Nontraditional Defense Contractor or Nonprofit Research Institution

	<ul style="list-style-type: none">• Offeror's Solution Brief has at least one Nontraditional Defense Contractor or Nonprofit Research Institute participating to a significant extent• All significant participants in the transaction other than the Federal Government are small businesses or Nontraditional Defense Contractors• Offeror provides at least one third of the total project cost as acceptable cost share
FAIL	<p>Offeror proposing an MTEC research project does NOT meet any of the following:</p> <ul style="list-style-type: none">• Offeror is a Nontraditional Defense Contractor or Nonprofit Research Institution• Offeror's Solution Brief has at least one Nontraditional Defense Contractor or Nonprofit Research Institute participating to a significant extent• All significant participants in the transaction other than the Federal Government are small businesses or Nontraditional Defense Contractors• Offeror provides at least one third of the total project cost as acceptable cost share

Based on the results of the evaluation of the Solution Brief, the Solution Brief Pitch and Cost Proposal, Offerors may be selected for funding, recommended for the basket (if funding currently is unavailable) or not selected. At the conclusion of each proposal evaluation (for Step 1 & Step 2), Offerors will receive both a notification of the overall recommendation (select, basket, or non-select) and a summary of the Government's technical evaluation.

The RPP review and award process may involve the use of Government contractor support personnel serving as nongovernmental advisors in the case that they are considered subject-matter-experts; where appropriate, the U.S. Government (USG) will employ NDAs to protect information contained in the RPP as outlined in Section 2.6.

8 Points-of-Contact

For inquiries, please direct your correspondence to the following contacts:

- Questions concerning contractual, cost or pricing related to this RPP should be directed to the MTEC Contracts Administrator, mtec-contracts@ati.org
- Technical and membership questions should be directed to the MTEC Director of Research, Dr. Lauren Palestrini, Ph.D., lauren.palestrini@officer.mtec-sc.org
- All other questions should be directed to the MTEC Director of Program Operations, Ms. Kathy Zolman, kathy.zolman@ati.org

Once an Offeror has submitted a Solution Brief, the Government and the MTEC CM will not discuss evaluation/status until the source selection process is complete.

9 Acronyms/Abbreviations

ACURO	U.S. Army Animal Use and Review Office
ATI	Advanced Technology International
CAS	Cost accounting standards
CFR	Code of Federal Regulations
cGMP	Current Good Manufacturing Practice
CM	Consortium Manager
CMA	Consortium Member Agreement
CRMRP	Clinical and Rehabilitative Medicine Research Program
DHA	Defense Health Agency
DHP	Defense Health Program
DoD	Department of Defense
FAQ	Frequently Asked Questions
F&A	Facilities and Administrative Costs
FDA	U.S. Food and Drug Administration
FY	Fiscal Year
G&A	General and Administrative Expenses
HRPO	Human Research Protections Office
IACUC	Institutional Animal Care and Use Committee
IP	Intellectual Property (e.g., patents, copyrights, licensing, etc.)
IRB	Institutional Review Board
IR&D	Independent Research and Development
JPC-8	Joint Program Committee-8
M	Millions
MPS	Milestone Payment Schedule
MTEC	Medical Technology Enterprise Consortium
NDA	Nondisclosure Agreement
OASD[HA]	Office of the Assistant Secretary of Defense for Health Affairs
OCI	Organizational Conflict of Interest
ODC	Other Direct Charges
ORP	Office of Research Protections, USAMRDC
OTA	Other Transaction Agreement
POC	Point-of-Contact
POP	Period of performance
PPG	Proposal Preparation Guide
R&D	Research and Development

RDA	Research, Development, and Acquisition
RDT&E	Research, Development, Test, and Evaluation
ROM	Rough Order of Magnitude
RPP	Request for Project Proposals
RTD	Return to duty
SC	Stem cell
SOW	Statement of Work
USAMRDC	U.S. Army Medical Research and Development Command
USG	U.S. Government, specifically the DoD

Attachment A: Statement of Work (SOW)

The SOW developed by the Lead MTEC member organization is intended to be incorporated into a binding agreement if the Solutions Brief is selected for award. If no SOW is submitted, there will be no award. The proposed SOW shall contain a summary description of the technical methodology as well as the task description, but not in so much detail as to make the contract inflexible. DO NOT INCLUDE ANY PROPRIETARY INFORMATION OR COMPANY-SENSITIVE INFORMATION IN THE SOW TEXT. The following is the required format for the SOW.

Statement of Work

Submitted under Request for Project Proposal (*Insert current Request No.*)

(Proposed Project Title)

Introduction/Background (*To be provided initially by the Offeror at the time of submission. Submitted information is subject to change through negotiation if the Government selects for funding.*)

Scope/Project Objective (*To be provided initially by the Offeror at the time of submission. Submitted information is subject to change through negotiation if the Government selects for funding.*)

This section includes a statement of what the project covers. This should include the technology area to be investigated, the objectives/goals, specific aims, and major milestones for the effort.

Requirements (*To be provided initially by the Offeror at the time of submission to be finalized by the Government based on negotiation of Scope/Project Objective.*)

State the technology objective or specific aim in the first paragraph and follow with delineated tasks required to meet the overall project goals. The work effort should be segregated into major phases, then tasks and identified in separately numbered paragraphs (similar to the numbered breakdown of these paragraphs). Early phases in which the performance definition is known shall be detailed by subtask with defined work to be performed. Planned incrementally funded phases will require broader, more flexible tasks that are priced up front, and adjusted as required during execution and/or requested by the Government to obtain a technical solution. Tasks will need to track with established adjustable cost or fixed price milestones for payment schedule. Each major task included in the SOW should be priced separately in the Cost Proposal. Subtasks need not be priced separately in the Cost Proposal.

Deliverables (*To be provided initially by the Offeror at the time of submission. Submitted information is subject to change through negotiation if the Government selects for funding.*)

Results of the technical effort are contractually binding and shall be identified herein. Offerors are advised to read the Base Agreement carefully. Any and all hardware/software to be provided to the Government as a result of this project shall be identified. Deliverables should be submitted in PDF or MS Office format. It must be clear what information will be included in a deliverable either through a descriptive title or elaborating text.

Milestone Payment Schedule *(To be provided initially by the Offeror at the time of submission. Submitted information is subject to change through negotiation if the Government selects for funding. The milestone schedule included should be in editable format (i.e., not a picture))*

The Milestone Payment Schedule should include all milestone deliverables that are intended to be delivered as part of the project, a planned submission date, the monetary value for that deliverable and any cost share, if applicable. For fixed price agreements, when each milestone is submitted, the MTEC member will submit an invoice for the exact amount listed on the milestone payment schedule. For cost reimbursable agreements, the MTEC member is required to assign a monetary value to each milestone. In this case, however, invoice totals are based on cost incurred and will not have to match exactly to the amounts listed on the milestone payment schedule.

The milestones and associated deliverables proposed should, in general:

- be commensurate in number to the size and duration of the project (i.e., a \$5M multi-year project may have 20, while a \$700K shorter term project may have only 6);
- not be structured such that multiple deliverables that might be submitted separately are included under a single milestone;
- be of sufficient monetary value to warrant generation of a deliverable and any associated invoices;
- include at a minimum Quarterly Reports which include both Technical Status and Business Status Reports (due the 20th of Mar, Jun, Sep, Dec), Annual Technical Report, Final Technical Report, and Final Business Status Report. Reports shall have no funding associated with them.
- Include appropriate regulatory research approvals (e.g. IACUC, ACURO, IRB, HRPO)
- Include in-progress reviews and critical decision points for continuation for funding.

Milestone No.	Significant Event/Accomplishments Description of Deliverables	Due Date	Total Program Funds	Total Cost Share
1				
2				
3				

Total				

Shipping Provisions *(The following information, if applicable to the negotiated SOW, will be finalized by the Government and the MTEC Consortium Manager based on negotiations)*

- The shipping address is:

Classified Shipments:

Outer Packaging

Inner Packaging

Reporting *(The following information, if applicable to the negotiated SOW, will be provided by the Government based on negotiation)*

- Quarterly Reports – The MTEC research project awardee shall submit a Quarterly Report which will include a Technical Status Report and a Business Status Report in accordance with the terms and conditions of the Base Agreement. (Required)
- Annual Technical Report – The project awardee shall submit an Annual Technical Report for projects whose periods of performances are greater than one year in accordance with the terms and conditions of the Base Agreement. (Required)
- Final Technical Report – At the completion of the Research Project Award, the awardee will submit a Final Technical Report, which will provide a comprehensive, cumulative, and substantive summary of the progress and significant accomplishments achieved during the total period of the Project effort in accordance with the terms and conditions of the Base Agreement. (Required)
- Final Business Status Report – At the completion of the Research Project Award, the awardee will submit a Final Business Status Report, which will provide summarized details of the resource status of the Research Project Award, in accordance with the terms and conditions of the Base Agreement. (Required)
- Quad Charts – The project awardee shall submit a quad chart on a quarterly basis using Attachment E template.

Attachment B: Solution Brief Budget Summary Form

Sufficient cost information to substantiate the proposed cost as realistic and reasonable for the proposed effort must be provided to ensure that a complete and fair evaluation of the cost or price can be conducted. **Use the example table format and template below to provide an initial Budget.** The labor, travel, material costs, other direct costs, and indirect costs, information should be entered for Offeror (project prime) only. Subcontractors and/or consultants should be included only in the "Subcontractor" section of the table.

STEP 1 SOLUTION BRIEF BUDGET SUMMARY FORM

Cost Estimate for Year 1

Name of Principal Investigator (*last, first, middle*)

BUDGET					FROM	THROUGH	
PERSONNEL		TITLE/ POSITION	ANNUAL BASE SALARY	% EFFORT ON PROJECT	DOLLAR AMOUNT REQUESTED (OMIT CENTS)		
NAME	ROLE ON PROJECT				SALARY REQUESTED	FRINGE BENEFITS	TOTALS
	PI						
SUBTOTALS →→→→→							\$
CONSULTANT COSTS							
MAJOR EQUIPMENT (ITEMIZE)							
MATERIALS, SUPPLIES, AND CONSUMABLES (ITEMIZE BY CATEGORY)							
RESEARCH-RELATED SUBJECT COSTS							
TRAVEL							

Request for Project Proposals MTEC-20-07-QualRegen
Number W81XWH-15-9-0001

OTHER DIRECT COSTS (ITEMIZE BY CATEGORY)		
SUBTOTAL DIRECT COSTS FOR THIS BUDGET PERIOD →→→→→		\$
SUBCONTRACT COSTS	DIRECT COST	
	INDIRECT COST	
TOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD		\$
TOTAL INDIRECT COSTS FOR INITIAL BUDGET PERIOD		\$
TOTAL DIRECT AND INDIRECT COSTS FOR THIS BUDGET PERIOD		\$
FEE (NOT APPLICABLE IF COST SHARE IS PROPOSED)		\$
COST SHARE (IF COST SHARE IS PROPOSED THEN FEE IS UNALLOWABLE)		\$
TOTAL COSTS FOR THIS BUDGET PERIOD		\$

•

Name of Principal Investigator (*last, first, middle*)

DETAILED BUDGET FOR ENTIRE PROPOSED PERIOD OF SUPPORT							
BUDGET CATEGORY TOTALS ¹		INITIAL BUDGET PERIOD <small>(FROM FORM PAGE 1)</small>	ADDITIONAL YEARS OF SUPPORT REQUESTED				
			2nd	3rd	TOTAL		
PERSONNEL							
FRINGE BENEFITS							
CONSULTANT COSTS							
MAJOR EQUIPMENT							
MATERIALS, SUPPLIES, AND CONSUMABLES							
SUBJECT-RELATED COSTS							
TRAVEL							
OTHER DIRECT COSTS							
SUBTOTAL DIRECT COSTS							
SUBCONTRACT COSTS	DIRECT						
	INDIRECT						
TOTAL DIRECT COSTS							
TOTAL INDIRECT COSTS							
FEE (NOT APPLICABLE IF COST SHARE IS PROPOSED)							
COST SHARE							
TOTAL DIRECT COSTS FOR ENTIRE PROPOSED PERIOD OF SUPPORT						\$	
TOTAL INDIRECT COSTS FOR ENTIRE PROPOSED PERIOD OF SUPPORT						\$	
TOTAL FEE FOR ENTIRE PROPOSED PERIOD OF SUPPORT							
TOTAL COST SHARE FOR THE PROPOSED PERIOD OF SUPPORT							
TOTAL COSTS FOR THE ENTIRE PROPOSED PERIOD OF SUPPORT THIS AMOUNT SHOULD AGREE WITH THAT ENTERED IN THE REQUIRED FILES						\$	

Attachment C: Biosketches

Biographical Sketch

Provide the following information for each individual included in the Research & Related Senior/Key Person Profile (Expanded) Form.			
NAME		POSITION TITLE	
EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training).			
INSTITUTION AND LOCATION	DEGREE (IF APPLICABLE)	YEAR(S)	FIELD OF STUDY

RESEARCH AND PROFESSIONAL EXPERIENCE: Concluding with present position, list in chronological order, previous employment, experience, and honors. Include present membership on any Federal Government public advisory committee. List in chronological order the titles, all authors, and complete references to all publications during the past 3 years and to representative earlier publications pertinent to this application. If the list of publications in the last 3 years exceeds 2 pages, select the most pertinent publications. PAGE LIMITATIONS APPLY. DO NOT EXCEED 5 PAGES FOR THE ENTIRE BIOGRAPHICAL SKETCH PER INDIVIDUAL.

Attachment D: Data Rights

The Offeror shall comply with the terms and conditions defined in the Base Agreement regarding Data Rights.

It is anticipated that anything delivered under this proposed effort would be delivered to the Government with Government purpose data rights or unlimited data rights. If this is not the intent, then the proposal should discuss data rights associated with each item, and possible approaches for the Government to gain Government purpose data rights or unlimited data rights as referenced in the Base Agreement. Rights in technical data in each Research Project Award shall be determined in accordance with the provisions of MTEC Base Agreement.

If applicable, complete the below table for any items to be furnished to the Government with restrictions. An example is provided.

Technical Data or Computer Software to be Furnished with Restrictions	Basis for Assertion	Asserted Rights Category	Name of Organization Asserting Restrictions	Milestone # Affected
Software XYZ	Previously developed software funded exclusively at private expense	Restricted	Organization XYZ	Milestones 1, 3, and 6
Technical Data Description	Previously developed exclusively at private expense	Limited	Organization XYZ	Milestone 2
Technical Data Description	Previously developed with mixed funding	Government Purpose Rights	Organization XYZ	Milestone 2

Attachment E: Quad Chart Template

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Refer to the Members-Only Site or the MTEC website's current solicitations webpage (<https://www.mtec-sc.org/solicitations/>) for the quad chart template.

Attachment F: Current and Pending Support

For Information Only – Stage 2 Requirement

Current

Award Number:

Title:

Funding Agency/Requiring Activity:

Dates of Funding:

Total Direct Costs:

Role: *(i.e. Principal Investigator, Co-Investigator, etc.)*

Brief summary of the scope of work:

Award Number:

Title:

Funding Agency/Requiring Activity:

Dates of Funding:

Total Direct Costs:

Role: *(i.e. Principal Investigator, Co-Investigator, etc.)*

Brief summary of the scope of work:

[Add additional fields, if needed, to report all current support]

Pending

Title of Proposal:

Funding Agency/Requiring Activity:

Estimated Dates of Funding:

Proposed Total Direct Costs:

Role: *(i.e. Principal Investigator, Co-Investigator, etc.)*

Brief summary of the scope of work:

Title of Proposal:

Funding Agency/Requiring Activity:

Estimated Dates of Funding:

Proposed Total Direct Costs:

Role: *(i.e. Principal Investigator, Co-Investigator, etc.)*

Brief summary of the scope of work:

[Add additional fields, if needed, to report all pending support]