Medical Technology Enterprise Consortium (MTEC)

Request for Project Proposals

Medical Technology Enterprise Consortium SM

Solicitation Number: MTEC-16-01-REGEN

Issued by:

Advanced Technology International,
dba SCRA Applied R&D
MTEC Consortium Manager
315 Sigma Drive
Summerville, SC 29486
for the
Medical Technology Enterprise Consortium (MTEC)

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Proposal Due Date: April 15, 2016
12:00PM Eastern Daylight Time

White papers Not Required

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Executive Summary

1.1 Purpose

The Medical Technology Enterprise Consortium (MTEC) has been established as 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 Materiel Command (USAMRMC) and other Government agencies in the biomedical sciences (including but not limited to drugs, biologics, vaccines, medical software and medical devices) to protect, treat and optimize the health and performance of U.S. military personnel. MTEC has been formed as 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 and follow-on production.

Applications for this Request for Project Proposals (RPP) are being solicited for the Defense Health Agency, Research, Development and Acquisition (DHA RDA) Directorate. As directed by the Office of the Assistant Secretary of Defense for Health Affairs (OASD[HA]), the DHA RDA Directorate manages the Defense Health Program (DHP) Research, Development, Test, and Evaluation (RDT&E) appropriation. This solicitation, issued by the MTEC Consortium Manager (CM), Advanced Technology International, dba SCRA Applied R&D, represents an RPP for MTEC's support of the Clinical and Rehabilitative Medicine Research Program (CRMRP) technology objectives. Strategic oversight for the award(s) supported via this RPP will be provided by Joint Program Committee 8(JPC-8)/CRMRP. To address the President's Advanced Manufacturing Partnership, funds are being made available to support emerging technologies and foster a domestic manufacturing capability that could increase jobs and position the U.S. as a leader in specific domains. As such, funds from the DHP RDT&E appropriation are being made available to advance the state-of-the-art in biomedical manufacturing, consistent with the National Strategic Plan for Advanced Manufacturing (https://www.whitehouse.gov/sites/default/files/microsites/ostp/iam_advancedmanufacturing_strategicplan_2012.pdf). Specifically, funds are to support areas of regenerative medicine manufacturing and prototyping that require development and harmonization into reproducible, consistent procedures which could stand the test of U.S. Food and Drug Administration (FDA) approval. This emerging area of medical technology and innovation suffers from the lack of standard manufacturing procedures that support this combination product line. This initiative is intended to have a period of performance of up to **5 years**. Outcomes from this initiative are anticipated to result in well-defined and sufficiently advanced prototypes and manufacturing technologies that may be included in regulatory applications seeking FDA approval.

As the solicitation will describe, MTEC has bucketed the potential areas of improvements, and hence proposals, for this requirement into five categories. MTEC believes all of these

areas currently present roadblocks to regenerative medicine prototype development and product manufacturing that will need to be addressed over the life span of the funding, and MTEC will endeavor to balance the portfolio of projects across all these areas as best as possible. These are as follows:

1. Development of universal, defined culture media for regenerative medicine;
2. Bioreactors to enable efficient and cost-effective cell and tissue expansion for regenerative medicine products;
3. Cell, tissue, and product preservation for regenerative and personalized medicine;
4. Large scale manufacturing and quality assurance of regenerative medicine products;
5. Dynamic and innovative quality assurance for regenerative medicine manufacturing.

Later within the solicitation these areas will be described in more detail, and specific examples will be provided of the type of actions that are being requested. Any of these areas may be selected as potential areas for a proposal focus.

As funds are being made available through the DHP RDT&E appropriation, military relevance is a critical component of proposal submission. The CRMRP focuses on innovations to reconstruct, rehabilitate, and provide definitive care for injured Service members. The ultimate goal is to return the Service members to duty and restore their quality of life. Innovations developed from CRMRP-supported research efforts are expected to improve restorative treatments and rehabilitative care to maximize function for return to duty (RTD) or civilian life. The CRMRP 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, 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 CRMRP 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. This MTEC RPP is focused on the clinical, prototyping, and manufacturing needs of the regenerative medicine research and development portfolio.

Though advancement in prototype development and manufacturing practices is the primary goal, the product being advanced should have relevancy to the military's regenerative medicine needs. Offerors who wish to advance prototype development and manufacturing process standardization called for in this solicitation should use regenerative medicine product lines that are within the groups below for their sample materiel. In that manner, the project requirement includes two simultaneously critical

objectives: 1) improving the manufacturing process; and, 2) making available product for applied research or clinical studies.

In order to qualify for an award under this RPP, the project must fall within the prescribed areas of military need which has a manufacturing component aspect to continue its development. Example areas of military need are: composite tissue regeneration, vascular repair/revascularization, nerve regeneration, bone regeneration, muscle protection/regeneration, treatment of burns and large skin injuries, immunomodulation, and regeneration of the genitourinary system.

The manufacturing effort is the primary driver, but that product which will be produced within the manufacturing processes and validation testing should be one that meets military need. A couple of factors become evident when seen through this perspective.

- Later stage projects would be the most relevant to this solicitation. Later stage projects have a far greater need for this type of manufacturing scale up and standardization to support the project development plan. MTEC, therefore, expects that projects should be either entering formal FDA supportive clinical trials or working within defining animal studies for upcoming regulatory submission to the FDA. This is not meant to support pilot lot manufacturing for animal study purposes.

- It is expected that many of the actual regenerative medicine projects may still be at the academic level, yet the manufacturing requirements demanded are most suited to industry. MTEC, therefore, considers that a teamed approach may have the greatest level of success, especially considering that the eventual goal is to transition products to industry for FDA approval.

Finally, another factor that should be considered is the dual use opportunity of this work. The funds provided for this biomanufacturing initiative are to prime the pump for such efforts, but are not anticipated to be the sole funding resource for the efforts. Because the area is largely focused at the industry prototyping and manufacturing capabilities, rather than academic discovery actions, it is anticipated that the Government funds would provide incentive for industry funding to join the project. While not a requirement, Offerors are strongly encouraged to discuss outside funding potential prior to submitting proposals.

1.2 Request for Project Proposals

Each MTEC research project proposal submitted must contain both a Technical and Cost Proposal Volume as described in Section 3 of this request and must be in accordance with the mandatory format provided in the MTEC Proposal Preparation Guide (PPG), which is available on the Members Only portion of the MTEC website at www.mtec-sc.org. ***White papers are not required for this RPP.*** The Government reserves the right to award proposals received from this RPP on a follow-on Other Transaction Agreement (OTA) or other stand-alone OTAs as necessary to meet mission requirements.

1.3 Funding Availability and Type of Funding Instrument Issued

The CRMRP/JPC-8 expects to allot approximately $20M of the FY15-FY16 DHP RDT&E appropriation to support proposals received in response to this RPP. Funding is dependent on the quality and number of proposals received. In addition to the FY15-16 DHP RDT&E appropriations, it is anticipated that up to $30M in future year DHP RDT&E funds may be available to support awards made under this RPP. 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. Funding of proposals received in response to this RPP is contingent upon the availability of federal funds for this program.

The Government-selected research project awards will be funded under the Other Transaction Agreement Number W81XWH-15-9-0001 (or subsequent OTAs in support of MTEC) with MTEC administered by the CM, SCRA Applied R&D. The CM will negotiate and execute a Base Agreement with MTEC members. This Base Agreement will be governed by the same provisions as the OTA between the Government and MTEC. Subsequently, any proposal that is selected for award will be funded through a Research Project Award issued under the Base Agreement. A sample of the MTEC Base Agreement can be found on the Members Only portion of the MTEC 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 proposals 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 proposals that, if selected for award, it anticipates the proposed effort will be funded under its executed MTEC Base Agreement No. 20XX-XXX.

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

1.4 Proprietary Information

The MTEC CM will oversee submission of proposals and analyze cost proposals submitted in response to this RPP. The CM shall take the necessary steps to protect all proprietary proposal 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. An Offeror's submission of a proposal under this RPP indicates concurrence with the aforementioned CM responsibilities.

1.5 Offeror Eligibility

Offerors must be MTEC Members in good standing.

1.6 Inclusion of Nontraditional Defense Contractors

Section 815 of the National Defense Authorization Act (NDAA) for Fiscal Year 2016 authorizes Department of Defense organizations to carry out prototype projects that are directly relevant to enhancing the mission effectiveness of military personnel and the supporting platforms, systems, components, or materials proposed to be acquired or developed by the Department of Defense, or to improvement of platforms, systems, components, or materials in use by the armed forces.

Proposals that do not include nontraditional defense contractor participation to a significant extent, or do not propose at least one third acceptable cost sharing, will not be eligible for award. Please see the MTEC Proposal Preparation Guide for additional details.

1.7 Cost Sharing

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 as discussed in the MTEC PPG. If the offer contains multiple team members, this information shall be provided for each team member providing cost share. For additional information regarding cost share, please see the Cost Share Guidance document on the MTEC website www.mtec-sc.org.

1.8 Expected Award Date

Offeror should plan on the period of performance beginning mid August, 2016. 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.

1.9 Anticipated Proposal Selection Notification

As the basis of selections are completed, the Government will forward their selections to the CM for notification of Offerors.

2 Full Proposal

2.1 Full Proposals

Full Proposals in response to this Request for Research Project Awards must be received by the date on the cover page of this RPP. Proposals received after the time and date specified will not be evaluated.

The MTEC PPG is specifically designed to assist Offerors in understanding the proposal preparation process. The proposal format provided in the MTEC PPG is mandatory. MTEC will post any general questions received and corresponding answers (without attributable proprietary data) on the members only MTEC website.

2.2 Proposal Submission

Offerors must submit proposals via email to mtec-sc@mtec-sc.org

2.2.1 Submission Format

Offerors should 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.

- **Full technical proposal submission:** one Word (.docx or .doc) or PDF file Separately, a Word (.docx or .doc) version of the SOW (Appendix B of the proposal) is required.
- **Full cost proposal submission:** one Word (.docx or .doc) or PDF file for Section I: Cost Proposal Narrative required. Separately, Section II: Cost Proposal Formats 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.

MTEC will email receipt confirmations to Offerors upon submission of proposals and will include a unique reference number. Offerors may submit proposals in advance of the deadline.

3 Proposal Preparation Instructions

3.1 General Instructions

Technical and cost proposals must be submitted in separate volumes, and shall remain valid for 180 days unless otherwise specified by the Offeror in the proposal. **The proposal format provided in the MTEC PPG is mandatory.** Proposals shall reference this RPP number (MTEC-16-01-REGEN).

Offerors are encouraged to contact the POC identified herein up until the proposal submission date/time to clarify requirements.
For this RPP, Offerors may submit multi-year proposals not to exceed five years. Offerors are to propose a Milestone Payment Schedule which 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. 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).

All eligible Offerors may submit proposals for evaluation according to the criteria set forth herein. Offerors are advised that only SCRA Applied R&D as the MTEC's CM, with the approval of the Governments Agreements Officer, is legally authorized to contractually bind or otherwise commit funding for selected Research Project Awards as result of this RPP.

3.2 Technical Proposal and Statement of Work

3.2.1 Technology Objectives

The JPC-8/CRMRP, 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 FDA and European Medicines Agency to provide patients with clinical-grade products that are safe and have defined quality characteristics. However, 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 many factors which need to be developed and advanced, including (1) development of universal, defined culture media, (2) advancing bioreactor technology for cost-effective cell and tissue expansions, (3) improving cell, tissue, and organ preservation technology, (4) innovating and advancing large scale manufacturing and quality assurance for regenerative medicine based products, and (5) developing dynamic and innovative quality assurance strategies for regenerative medicine manufacturing. Based on this, the major objective of this solicitation is to develop scalable, production-ready, commercial prototypes and processes for cell, tissue, or organ bioengineering technologies that will overcome current challenges and enable successful cGMP manufacturing and clinical translation of regenerative medicine based therapies. Technologies of interest include, but are not limited to, the following:

1. Development of universal, defined culture media for regenerative medicine

Many regenerative medicine products, particularly for musculoskeletal applications, include a cellular component. The cellular component is typically derived from an autologous or allogeneic source. These cells are living products that are passed through a variety of processing steps, including biopsy, cell banking, expansion and scale-up, storage, and distribution. Throughout these many processing steps, the complex mixture of culture media can significantly vary among cell types and process steps (e.g., expansion, cryopreservation, differentiation). In addition, serum is also a very complex mixture containing xenogeneic ingredients, where batch-to-batch consistency is of great concern and

often has unwanted effects on the optimal production of cells. Therefore, there is a need to develop universal, xeno-free media formulations for cell types commonly used in regenerative medicine products. In addition, GMP-quality human enzymes or extracellular matrix proteins should be used if required during the process. Specific areas of interest include, but are not limited to, the development of:

- Xeno-free serum
- Xeno-free defined cell medium for cell growth, selection and expansion, differentiation, storage and distribution, and specimen harvest

2. Bioreactors to enable efficient and cost-effective cell and tissue expansion for regenerative medicine products

For many regenerative medicine therapies, millions of cells are required for each patient. The cell and tissue expansion phase of the manufacturing process is by far the most expensive and time consuming step, often requiring several months to reach economically-viable numbers of cells. There is a significant need for alternatives to flat plate culture technologies for efficient and cost-effective cell and tissue expansion. Areas of interest to enhance cell expansion for regenerative medicine products include, but are not limited to:

- Scale-up of commonly used cell types with defined quality characteristics into 10L, 50L, and 100L bioreactors
- Non-invasive or minimally-invasive in-process technologies that can monitor key parameters of the expansion process, including but not limited to: cell viability, cell number, endotoxin content, mycoplasma
- Non-destructive cell harvesting technologies
- Single-use bioreactors for the scale-up of cells
- Infrastructure to allow cell expansion to occur in parallel
- Cell purification processes
- Scale up the production of organoids for industrial use

3. Cell, tissue, and product preservation for regenerative and personalized medicine

Biobanking and biopreservation offers the possibility to preserve cells and tissue sources for future use. For regenerative and personalized medicine, these cells and tissues are later developed into products that need to be preserved to maintain activity during production, through manufacturing release, and ultimately to patient application. Therefore, there is a need to develop advanced, cost-effective technologies and processes for banking cells and tissues, and preserving regenerative medicine-based products to assist with shipping and distribution. Areas of interest include, but are not limited to:

- Novel preservation methods (e.g., non-cryogenic) that can be used on tissue engineered products during storage, shipping and distribution (including adverse environments such as austere conditions)

- Advanced systems and processes for cell and tissue preservation, including specimen harvest, cell retrieval, and tissue-typing
- Tests or methods to analyze or determine cell, tissue, or product viability/function following short-term and long-term storage

4. Large scale manufacturing and quality assurance of regenerative medicine-based products

Regenerative medicine products in early development are often fabricated using laboratory-based processes and lack defined product specifications. Therefore, the intent of this area of interest is to transfer these laboratory-based processes into scalable, production-ready, commercial manufacturing processes for cell, tissue, or organ bioengineering products with defined acceptance criteria. Specific areas of interest include, but are not limited to:

- Scalable, production-ready, commercial additive manufacturing, such as 3D printing for regenerative medicine applications
- Automated tissue digestion systems
- High throughput cell sorting technology
- High throughout cell separation/isolation from media
- Automated manufacturing processes for regenerative medicine products (scaffolds and/or bioactive molecules and/or cells)
- Develop large scale systems capable of screening and engineering adult stem cells

5. Dynamic and innovative quality assurance strategy for regenerative medicine manufacturing

The identification and specification of standards and acceptance criteria are important for the regulatory approval of all implantable, manufactured products. Regenerative medicine-based products tend to have qualitative product acceptance criteria, which are difficult to standardize. Therefore, there is a need to develop and advance methods for quality assurance to assess process changes in regenerative medicine product manufacturing as well as in cell, tissue, and bioengineered organ product characteristics and function. Areas of interest to enhance the quality assurance strategy of regenerative medicine products include, but are not limited to:

- Systems that can provide rapid batch testing for the evaluation of a production run
- Automated and non-destructive imaging systems for inspection and characterization of tissue engineered products
- Non-destructive in-process technologies that can monitor key parameters of the manufacturing process

3.2.2 Military Relevance:

Though advancement in prototyping and manufacturing impact areas is the primary objective of this funding opportunity, relevance to the health care needs of military Service members, Veterans, and/or other Military Health System beneficiaries are a key feature of this award. Provide a brief statement explaining the potential relevance of the proposed work to the military mission, health, medicine, and its impact on Service members, Veterans and their beneficiaries. Many of the military needs are also applicable to the civilian population. Technical areas of military relevance include, but are not limited to:

- Composite tissue regeneration (e.g., muscle, bone adipose, skin)
- Vascular repair/revascularization
- Regenerate nerve defects >3cm with 90% reliability
- Regenerate bone defects >3cm or bone nonunions with sufficient reliability
- Muscle protection/regeneration
- Close burns of greater than 40% total body surface area at a single operation
- Control scar formation
- Provide definitive closure of large wounds
- Ability to modulate the immune system for treatments that require immunomodulation
- Use of regenerative medicine to replace missing or damaged parts of the genitourinary system, such as the scrotum, kidney, bladder, penis, testicles, ureter, and urethra.
- Cell and tissue manufacturing for military working dogs.

3.2.3 Commercialization Plan and Regulatory Pathway

The successful Offeror will provide a description and justification of the anticipated regulatory pathway and commercialization plan. The Commercialization Plan should describe the strategy the Offeror will employ to move a technology to the military and civilian market. The plan provides a roadmap to convey how the Offeror may ultimately generate revenue and profits from the innovation, either from partnering to license and/or co-develop the technology, or continuing to develop internally with additional funds identified in conjunction with MTEC funding. The quality of the analysis within the Commercialization Plan is a critical element of the MTEC proposal review. Assumptions within the plan should be clearly stated, and evidence of validation should be provided. Include pertinent information about intellectual property. Describe the planned indication for the product label, if appropriate, and include an outline of the development plan required to support that indication. The application should describe a transition plan (including potential funding and resources) showing how the product will progress to the

next clinical trial phase and/or delivery to the market after the successful completion of this award. The Proposal Preparation Guide offers key questions to answer in completing the plan. The Commercialization Plan must concisely convey:

- A description and justification of the anticipated regulatory pathway
- The business opportunity enabled by the innovation
- The compelling value proposition for the intended customer
- The key points of a plan appropriate for the Offeror's stage of development
- The status of the effort to date
- The current as well as the anticipated commercial landscape
- Pertinent information about Intellectual Property
- The planned indication for the product label, if appropriate
- Transition plan (including potential funding and resources) showing how the product will progress to the next clinical trial phase and/or delivery to the market after the successful completion of this award
- The vision for the enterprise and how the proposed innovation fits into the future market.

3.3 Cost Proposal

The cost proposal must include the requested information indicated in the Cost Proposal Section of the MTEC PPG. MTEC will make sample cost proposal formats available on the members only MTEC website. Offerors are encouraged to use their own cost formats such that the necessary cost detail is provided. Refer to the program MTEC PPG for additional details.

3.4 Proposal Preparation Cost

The cost of preparing proposals in response to this RPP is not considered a direct charge to any resulting award or any other contract.

4 Selection

4.1 Proposal Source Selection

The Government will undertake proposal source selection. The proposal source selection will be conducted in accordance with the evaluation factors detailed below. The Government will conduct an evaluation of all qualified proposals. The Source Selection Authority may:

a) Select the proposal (or some portion of the proposal) for award

b) Place the proposal in the Basket if funding currently is unavailable or

c) Reject the proposal (will not be placed in the Basket)

4.2 Evaluation Process

All applications will be evaluated by a panel of subject matter experts that will make recommendations for funding to the DHA RDA Directorate and the OASD(HA) based on (a) criteria described below; and (b) the relevance to the missions of the DHP, JPC-8/CRMRP, CRMRP, and MTEC. Offerors submitting the best value proposals that meet the evaluation criteria will be selected for award negotiations.

Factor 1: Nontraditional Defense Contractor/Cost Sharing
Factor 2: Technical Benefit
Factor 3: Potential for Transition and Commercialization
Factor 4: Cost

Nontraditional Defense Contractor/Cost Sharing is more important than Technical Benefit. Technical Benefit is more important than Transition and Commercialization. Transition and Commercialization is more important than Cost.

The following adjectival merit ratings will be used for Factors 2 and 3:

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 unawardable.

4.2.1 Factor 1. Nontraditional Defense Contractor/Cost Sharing.

Each Offeror must have at least one Nontraditional Defense Contractor 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 Member Organization. See paragraph 1.6 for specific details on this evaluation criteria.

The following ratings will be used for Nontraditional Defense Contractor/Cost Sharing Evaluation:

Evaluation	**Rating**
Offeror proposing an MTEC research project meets at least one of the following: • Offeror is a Nontraditional Defense Contractor • Offeror's proposal has at least one Nontraditional Defense Contractor participating to a significant extent • Offeror provides at least one third of the total project cost as acceptable cost share	Acceptable
Offeror proposing an MTEC research project meets at least one of the following: • Offeror has at least one Nontraditional Defense Contractor participating, but additional detail is required to determine if nontraditional participation is significant • Offeror has proposed cost share, but additional detail is required to determine if cost share is acceptable	Marginal
Offeror proposing an MTEC research project does **not** meet any of the following: • Offeror is a Nontraditional Defense Contractor • Offeror's proposal has at least one Nontraditional Defense Contractor participating to a significant extent • Offeror provides at least one third of the total project cost as acceptable cost share	Unacceptable

Proposals receiving a rating of unacceptable will be rejected. Proposals that receive an overall Technical Benefit Factor rating above a "Marginal" but with a Nontraditional Defense Contractor/Cost Sharing rating of "Marginal" may be awarded only if and when nontraditional participation is deemed significant or one third cost share is proposed.

4.2.2 Factor 2: Technical Benefit

The Technical Benefit Merit Rating will be a subjective adjectival rating.
The overall Technical Benefit Merit Rating will be based on an integrated assessment of the criteria described below. Each criterion will receive an adjectival rating of Outstanding, Good, Acceptable, Marginal, or Unacceptable. Based on these adjectival ratings, an overall Technical Benefit Factor Rating will be determined. The Technical Benefit Evaluation criteria are as follows:.

1. Ability to address a specific Technology Objective area
2. Management, Schedule, Resources and Personnel

4.2.2.1 Ability to address a specific Technology Objective area

- The Offeror's proposed solution will be assessed for the likelihood of successfully achieving the requirements of the technology of interest as defined in the MTEC Technology Objectives. This likelihood of success will be determined by considering the soundness of the technical approach, including complete and clear processes to execute the effort. Additional consideration will be given to the degree to which any preliminary existing data supports the proposed project plan and objectives, and the suitability of the proposed statistical plan. The proposed road map and SOW should provide a feasible plan for addressing the project's objectives. The plan will be evaluated for how well the rationale, objectives, and specific aims support the research idea. The proposed effort will be assessed for the extent the solution is a technological breakthrough solution that is an innovative, novel approach, which is a brand new technology that currently is not readily available. A description of the proposed efforts demonstrated abilities to advance the technology maturity level and to demonstrate projected performance improvements will be assessed. Relevance to the health care needs of military Service members, Veterans, and/or other Military Health System beneficiaries and the extent to which the proposal offers a joint Service solution will be considered.

4.2.2.2 Management, Schedule, Resources and Personnel

The Offeror's proposal will be assessed for the aspects that evaluate the **Management, Schedule, Resources and Personnel**. The Offeror's proposal will be considered for

- Presentation of a sound management plan that demonstrates an ability to perform the proposed project in an orderly, timely manner.
- Degree to which the project team's expertise, key personnel, and corporate experience demonstrate ability to accomplish the SOW.
- Extent that facilities and resources are sufficiently identified and available to execute the effort as proposed.
- Clearly identified tangible technical benefits resulting from cost share resources above the required statutory requirement.
- Detailed schedule with cost risks, and potential mitigation strategies identified.

If clinical trials are proposed, the following elements will be assessed: 1) Study Design; 2) Statistical Plan and Data Analysis; 3) Description of Technical Risks; 4) Explanation of Ethical Issues; 5) Quality Management Plan; 6) Training and Proficiency Requirements for personnel; and 7) Development/Technical Reports. See PPG for descriptions of these elements.

4.2.3 Factor 3: Potential for Transition and Commercialization

The Offeror's proposal will be assessed for:

- How well the Offeror provides sufficient evidence that the effort is ready to move into the proposed stage of research, development, or clinical testing.
- How well the project will translate promising, well-founded basic or clinical research findings into clinical applications for military Service members and or their beneficiaries.
- How well the funding strategy described will advance the technology to the next level of development and/or delivery to the military or civilian market.
- How well the proposal identifies intellectual property ownership, describes any appropriate intellectual and material property plan among participating organizations (if applicable), and addresses any impact of intellectual property issues on product development.
- How well the regulatory strategy is described, if applicable.

4.2.4 Factor 4: Cost Evaluation Factors

The Cost area will receive a narrative rating. The Government Technical Evaluators will assess cost realism as part of the source selection process. If a proposal is selected for award, the MTEC CM will review the original cost proposal and the Offeror's response to a Proposal Update Letter (PUL), if applicable. The MTEC CM will request additional information or clarification as necessary. The MTEC CM will assess the reasonableness and completeness of the cost estimates and then provide a formal assessment to the Government. The Government will review this assessment and make the final determination that the negotiated project value is fair and reasonable.

Completeness

The following will be evaluated:

- The degree to which the Offerors have provided all cost information requested in the Request for Project Proposal. Rate and pricing information is required to properly perform the cost analysis of the proposal. If the Offeror is unwilling to provide this information in a timely manner, its proposal will be lacking information that is required to properly evaluate the proposal and the proposal cannot be selected for award.
- Substantiation of cost (i.e., supporting data and estimating rationale) for all elements.

Reasonableness
To be considered reasonable, the Offeror's cost estimate should be developed from applicable historic cost data. The Offeror should show that sound, rational judgment was used in deriving and applying cost methodologies. Appropriate narrative explanation and justification should be provided for critical cost elements. The overall estimate should be presented in a coherent, organized and systematic manner.

Realism
Estimates are "realistic" when they are neither excessive nor insufficient for the effort to be accomplished. Estimates must also be realistic for each task of the proposed project when compared to the total proposed cost. The MTEC CM will make a determination by directly comparing proposed costs with comparable current and historical data, evaluator experience, available estimates, etc. Proposed estimates will be compared with the corresponding technical proposals for consistency.

As part of its cost analysis, the factors of completeness, reasonableness, and realism will be reviewed as discussed below.

4.3 Best Value

The Government will conduct the source selection and MTEC CM will award the projects in Best Value sequence for each Technology Objective. If applicable, the Government will invoke a best value process to evaluate the most advantageous offer by considering and comparing factors in addition to cost or price. Based on the results of the Technical Evaluation, the Government reserves the right to negotiate and revise any or all parts of the SOW. Offerors will have the opportunity to concur with the revised SOW and revise cost proposals as necessary. Projects not initially awarded will be placed in the Basket in accordance with the Basket Provision.

Definitions

Strength - An aspect of an Offeror's proposal that has merit or exceeds specified performance or capability requirements in a way that will be advantageous to the Government during award performance.

Weakness - A flaw in the proposal that increases the risk of unsuccessful award performance.

Significant Strength - An aspect of an offeror's proposal that has appreciable merit or appreciably exceeds specified performance or capability requirements in a way that will be appreciably advantageous to the Government during award performance.

Significant Weakness - A flaw that appreciably increases the risk of unsuccessful award performance.

Deficiency - A material failure of a proposal to meet a Government requirement or a combination of weaknesses in a proposal that increases the risk of unsuccessful award performance to an unacceptable level.

5 Points of Contact

Questions concerning contractual, cost or pricing related to this RPP should be directed to the MTEC Program Manager, Polly Graham at SCRA Applied R&D via email to mtec-sc@mtec-sc.org.

Once an Offeror has submitted a proposal, neither the Government nor the MTEC CM will discuss evaluation status until the source selection process is complete.