

Request for Project Proposals



Solicitation Number: MTEC-17-09-Prototype Development for Extracorporeal Life Support (ECLS)

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

Request Issue Date: May 23, 2017

***Amendment 02 Proposal Due Date: July 14, 2017
Noon Eastern Daylight Time***

White Papers Are Not Required

Amendment No. 02 changes the Proposal due date to July 14, 2017 at Noon Eastern Daylight Time.

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1 Executive Summary

1.1 Purpose

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 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 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.

MTEC is openly recruiting members to join a broad and diverse biomedical consortium that includes representatives from large businesses, small businesses, contract research organizations, “non-traditional” government 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.

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 U.S. Army Medical Materiel Agency (USAMMA) technology objectives. Strategic oversight for the award(s) supported by this RPP will be provided by USAMMA.

TECHNICAL BACKGROUND: Current military conflicts have exposed service members to complex injuries and combat polytrauma. The signature injuries currently seen are combinations of blast injuries (improvised explosive devices), penetrating wounds (projectiles and gunfire) and blunt force trauma, often accompanied by hemorrhagic shock and infection. Each of these injuries put casualties at risk of multisystem organ failure, but in combination have led to alarming rates of respiratory and renal failure. The use of conventional lung rescue strategies on standard ventilators, including lung protective ventilation, airway pressure release ventilation (APRV- a ‘rescue’ ventilator mode) and proning, can prove challenging to rescue severe cases. Additionally, the lack of expertise, equipment, and resources limit therapeutic capability.

The physiologic burden of injury-related sequela is not limited to the lungs, as renal failure occurs in up to 12.5% of patients¹ and contributes to mortality in nearly 30% of combat casualties.² A combination of shock, prolonged hypotensive resuscitation, and tissue damage from a blast lead to rhabdomyolysis, acute kidney injury, and renal failure. Temporary renal replacement therapy can be lifesaving in these cases, as untreated traumatic renal failure has an unacceptably high mortality.^{3,4,5}

In an effort to address these critical gaps in the most injured casualties, several strategies have emerged. An extracorporeal membrane oxygenation (ECMO) lung rescue team currently exists that can be launched from the US to any Role 3 facility on the battlefield. This team has the expertise and is equipped to be able to cannulate patients on site and initiate full ECMO. ECMO is a strategy to bring the blood of the patient outside of the body, through a circuit that will add oxygen and remove carbon dioxide, bypassing the compromised lung. ECMO generally requires large cannulas that can accommodate blood flows up to 5 L/min and requires specialized training. For renal failure, several Role 3 level assets have temporary renal replacement therapy (RRT) capability. Temporary RRT functions similar to ECMO, but operates at much lower blood flows (200-400 ml/min). Carbon Dioxide (CO₂) removal operates at similar flow rates as RRT and uses the same catheter sizes. This partial lung support can protect the lungs from injurious ventilation and has the potential to allow for avoidance of ventilation entirely. There are emerging uses for this therapy in trauma and combat casualty care, but it requires a more robust regulatory strategy at this time.

With the changing landscape of combat operations, and the mandate to provide up to 72 hours of prolonged care in the field, sicker patients will present to forward deployed MTFs. These patients have potential for significant ischemia-reperfusion injury with resultant AKI and acute respiratory distress syndrome (ARDS). Therefore, there is a critical need to develop a single 'bridge' extracorporeal life support (ECLS) device that can be used in patients with both AKI and ARDS. The goal of this bridge therapy is to keep patients alive until more definitive support and transport can be achieved. This device must be able to fully support CO₂ removal while replacing the function of the kidneys through a standard dialysis catheter.

Though the military would most likely use the bridge ECLS device at a level 3 hospital facility, where more robust resources allow for adequate staffing, there may be a need to push farther forward, to the Role 2 if necessary, depending on the availability of evacuation assets. A device to meet the requirements would need to be lightweight, rugged, modular, and user-friendly for

¹ Stewart et al. (2016). Acute Kidney Injury in Critically Injured Combat Veterans: A Retrospective Cohort Study. *Am J Kidney Dis*, 68(4): 564-70.

² Gomez et al. (2009). Causes of mortality by autopsy findings of combat casualties and civilian patients admitted to a burn unit. *J Am Coll Surg*, 208(3): 348-54.

³ Chung et al. (2008). Renal replacement therapy in support of combat operations. *Crit Care Med*, 36(7 Suppl): S365-9.

⁴ Smith et al. (1955). Post-traumatic renal insufficiency in military casualties. II. Management, use of an artificial kidney, prognosis. *Am J Med*, 18(2): 187-98.

⁵ Teschan, P.E. (1992) Acute renal failure during the Korean War. *Ren Fail*, 14(3): 237-9.

implementation in both the field and for transport during fixed or rotary wing medical evacuation. The device would also have to be designed for use by any critical care medical provider with minimal training. Ideally, such a device could be scalable, allowing for full ECMO capability at higher echelons of care.

Finally, the device would have to be air worthy. Air worthiness is determined using standards that allow equipment to be flown in air evacuation platforms, such as a sturdy frame that can withstand vibration, elevation changes, and rapid turning, a sealed container that can withstand environmental elements, and the low emission of electronic signals that do not interfere with airframe avionics. (These standards are available from the U.S. Army Aeromedical Research Laboratory (USAARL) at Fort Rucker, AL at the following link: [http://www.usaarl.army.mil/pages/research/aced/documents/JECETS%20-%201Mar2012%20\(PA%20approved\)](http://www.usaarl.army.mil/pages/research/aced/documents/JECETS%20-%201Mar2012%20(PA%20approved)))

FOLLOW-ON: The intent of the Government is to develop and procure such an ECLS device. Therefore, the Government reserves the right to continue development of an ECLS prototype resulting from this RPP through a separate Other Transaction Agreement (OTA) or other agreement as necessary. Obviously the degree that a prototype meets the stated clinical requirements as well as its utility in multiple field locations will dictate if further action is taken after this solicitation effort.

MILITARY RELEVANCE: Military relevance is a critical component of proposal submission. The USAMMA is a unique and multifaceted organization that acts as the Army Surgeon General's central focal point and Executive Agent for strategic medical logistics programs and initiatives. The Agency's mission is to develop, acquire, provide, and sustain world class solutions and capabilities to enable medical readiness globally. Project Management Office, Medical Devices (PMO-MD) provides lifecycle management of advanced development and commercial medical devices supporting field medical organizations globally. This PMO provides oversight for technology, engineering, and manufacturing development efforts utilizing Defense Health Program (DHP) and Army Research, Development, Test and Evaluation (RDT&E) funds.

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 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 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 U.S. Government (USG) estimates funding amounts for Fiscal Year (FY) 2016 (FY16) and FY 2017 (FY17) for a potential total of \$2M. MTEC estimates up to 2 awards at \$1M each. The initial period of performance will be 12 months, with potential follow-on prototype maturation.

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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.

Award funding will be structured incrementally and based upon completion of milestones.

MTEC anticipates that awards will be made to a qualified team composed of multi-disciplinary teams, with multiple investigators/institutions responsible for partnering with the USG to accomplish all tasks. 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. Any potential follow-on work will most likely be a non-competitive follow-on to this project awardee.

All funding is intended for Research and Development and has a 2 year obligation period. As a result, MTEC must maintain strict oversight of timeline compliance to ensure that funding remains available for disbursement.

The intent of the Government is to develop and procure such an ECLS device for use within its deployed medical forces.

The Government-selected Research Project Awards will be funded under the Other Transaction Agreement (OTA) Number W81XWH-15-9-0001 (or subsequent OTAs in support of MTEC) with MTEC administered by the CM, ATI. 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 USG 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 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 proposal 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 proposal preparation period for any changes to the MTEC Base Agreement terms and conditions as well as clarifications found in Frequently Asked Questions (FAQ) responses.

1.4 Proprietary Information

The MTEC CM will oversee submission of proposals and analyze cost proposals submitted in response to this RPP. The MTEC 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. Also, as part of MTEC's mission to incorporate philanthropic donations, MTEC frequently makes contact with private foundations that award grants for research and operate in research areas that are aligned with those of MTEC. These private foundations may be interested in reviewing proposals within their program areas, allowing for opportunities to attract supplemental funding sources. On your proposal Cover Page, please indicate your willingness to allow MTEC Officers access to your Technical Proposal for the purposes of engaging in outreach activities with these private foundations. MTEC Officers granted proposal access have signed Nondisclosure Agreements (NDAs) and Organizational Conflict of Interest (OCI) statements. Additionally, these MTEC Officers represent organizations that currently are not MTEC members, and therefore their parent organizations are not eligible to submit research project proposals, nor 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.

1.5 Offeror Eligibility

Offerors must be MTEC Members in good standing.

1.6 Inclusion of Nontraditional Defense Contractors

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. This requirement is a statutory element of the Other Transaction Authority and will be regarded as a pass/fail criterion during the Compliance Screening. Please see the MTEC PPG (Section 3.3.2) and RPP (Section 4), 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). *The extent of cost sharing is a consideration in the evaluation of proposals under Factor 2 (RPP Section 4.1.2).* 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; 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.).

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.

For additional information regarding Non-traditional Defense Contractors and Cost Sharing, please see the Cost Share Guidance document available on the Members-Only portion of the MTEC website www.mtec-sc.org.

1.8 Intellectual Property

Intellectual Property (IP) rights for MTEC Research Project Awards will be defined in the terms of an awardee's Base Agreement and resultant Task Orders. 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.

Each Offeror will select either the MTEC Additional Research Project Award Assessment or the Royalty Payment (available on the MTEC members only website), not both and submit a signed copy with the proposal. Summary explanations of each are provided below.

Consortium Member Agreement (CMA)

- MTEC members receiving MTEC funding agreements for research projects will be required to execute either a MTEC Royalty Payment, or pay an additional 2% assessment fee on the award. (Per Section 3.5 Additional Research Project Award Assessment).

Royalty Payment

- The awardee will be subject to a 10% royalty on all Net Revenues received from licensing/commercialization of the technology developed under the Research Project Award, capped at 200% of funding provided (Per Section 3.5.1 of the CMA).

Additional Research Project Award Assessment

- Member agrees to pay an additional research project award assessment of 2% to satisfy its obligations under Section 3.5.2 of the CMA. This is in addition to the 1% assessment fee for all Research Project Awards. Per Section 3.4 of the 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.

1.9 Expected Award Date

Offeror should plan on the period of performance beginning September 1, 2017 (subject to change). The Government reserves the right to change the proposed period of performance start date via the CM and prior to issuing a Research Project Award.

1.10 Anticipated Proposal Selection Notification

As the basis of selections is completed, the Government will forward their selections to MTEC CM to notify Offerors.

2 Full Proposal

2.1 Full Proposals

Full Proposals in response to this RPP, 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 including questioner's proprietary data) on the Members-Only MTEC website.

2.2 Proposal Submission

Offerors must submit proposals via email to mtec-sc@ati.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 A of the proposal).
- **Full 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 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. Offerors may submit proposals in advance of the deadline.

3 Proposal Preparation Instructions

3.1 General Instructions

The Technical Proposal and Cost Proposal must be submitted in two 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-17-09-ECLS).

Offerors are encouraged to contact the Point-of-Contact (POC) identified herein up until the proposal submission date/time to clarify requirements. Offerors are to propose a Milestone Payment Schedule which should include all significant event/accomplishments that are intended to be accomplished as part of the project, a planned completion date (based on months post award), the expected research funding expended towards completing that milestone, and any cost share, if applicable. The Milestones and associated accomplishments proposed should, in general, be commensurate in number to the size and duration of the project. A milestone is not necessarily a physical deliverable; it is typically a significant R&D event. Quarterly and final technical reports may be considered deliverables, but they are not milestones. Please include quarterly and final technical reports as part of the Milestone Payment Schedule, without an associated cost.

All eligible Offerors may submit proposals 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 Government 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

3.2.1 Technology Objectives

The overarching goal of this program is to provide a prototype for evaluation that complies with the following essential characteristics. **Proposals submitted to MTEC should clearly state how the proposed research provides an innovative solution to integrating CO₂ removal and RRT into a single ECLS device with the ability to use each mode separately.**

The Program Office envisions potential future battlefield scenarios of prolonged field care, which will result in the presentation of critically ill patients with AKI and ARDS far-forward on the battlefield. The response to this scenario will include deploying lightweight, rugged, user-friendly bridge ECLS devices to Field Hospitals (Role of Care 3) and to transport patients during fixed wing medical evacuation. These devices will partially replace the function of the lungs for patients with ARDS or other types of pulmonary failure, and/or of the function of the kidneys for patients with AKI.

Proposals must address the first five (5) of the following essential characteristics for the combined ECLS device:

1. Deliver a choice of therapies (including, but not limited to, continuous RRT and partial lung support) with the option of combined AKI and ALI therapies being conducted simultaneously.

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2. Have a reasonable regulatory approach toward Food and Drug Administration (FDA) market authorized device for use in controlling CO₂ exchange in critically ill patients with ARDS and perform hemofiltration, hemodialysis and/or ultrafiltration in critically ill patients with AKI. The development concept papers must describe the methodology for the proposed approach and why they believe it will be successful.
3. Lightweight (less than 45lbs). In addition, the device with its associated fluids and connections should be mountable onto a standard NATO litter system used to transport patients.
4. Capable of various flow rates (150ml/min – 500 ml/min) for CO₂ removal, with potential expansion to include oxygenation as in an ECMO application; and accommodate the use of a standard dialysis catheters (at least 13.5 F) and varying insertion lengths (15 and 24 cm).
5. Should not require a large logistical footprint to use (supplies, fluids, minimal O₂, etc.).
6. User-friendly during initiation and maintenance of therapy, where target operators are Physician Assistants and/or General Physicians. Device should also be easy to maintain with the fielded equipment and the skills of biomedical equipment technician.
7. A description of lifecycle considerations should be included in the Development Concept Paper, such as, additional research and development costs, FDA requirements, ease of production, environmental exposure, versatility, modularity, maximum utilization of off-the-shelf components, initial acquisition cost, maintenance and repair requirements, operating and support costs, training requirements, technical support and recycle/disposal.
8. Operate on AC and DC power (11-28 Volt DC, 100/220 Volt AC 50/60Hz).
9. Operate using a rechargeable battery power source (battery life of a minimum of 8 hours when fully charged/hot swappable; objective is 12-24 hours).
10. Capable of passing airworthiness requirements for fixed and rotary wing medical evacuation. Airworthiness testing is conducted by the US Army Aeromedical Research Laboratory at Fort Rucker, AL.
11. Ruggedized for battlefield use (able to withstand temperature extremes (hot & cold), drops/vibration, dust/rain/humidity as outlined in MIL-STD-810G).
12. Easy to transport and secure in place upon aircraft and in a medical treatment facility.
13. Patient data generated from the device should be transferable via either a tethered or wireless means to computer or hand held devices and should follow Health Level 7-related standards as defined by the DoD Healthcare Management System Modernization.

Upon completion of the 12 month period of performance, each prototype will be evaluated in an *in vivo* performance challenge conducted by a DOD intramural lab headed by Dr. Andriy Batchinsky (United States Army Institute of Surgical Research). Each awardee will be expected to attend the challenge to setup, operate, and breakdown their prototypes. The description of the animal model that will be used for the *in vivo* performance challenge can be found here: (add ref

to paper(s)). Travel funds for participation in the *in vivo* performance challenge will be provided for team members in addition to the \$1M provided for the prototype build. The challengers will receive the results of the *in vivo* performance challenge within 30 days of completion of the study. Please note that as part of the \$1M work plan, Offerors are allowed to propose animal studies to demonstrate proof-of-concept of the various prototype requirements and prepare for the aforementioned *in vivo* performance challenge. Offerors are encouraged to communicate with Dr. Andriy Batchinsky during the preparation of their proposals to include animal studies that best prepare the prototype for the *in vivo* performance challenge. Dr. Batchinsky's email address is: andriy.i.batchinsky.ctr@mail.mil.

MTEC seeks proposals from investigators comprising multi-disciplinary teams from a wide spectrum of disciplines including, but not limited to, engineering, translational research, and clinical research.

Proposed projects must be based on logical reasoning and sound scientific rationale. Please note that awards are not to be exploratory in nature and require a foundation of preliminary data.

Caveat: Although the overarching critical specifications of the combined renal and lung support prototype device are outlined above, we encourage you to submit even if you cannot currently meet all these specifications within this time frame. We have prioritized the characteristics in order of importance; therefore, we would potentially consider lesser responses based upon the parameters that could be met and the teams' approach to meeting the other characteristics over time. However, it is expected that an Offeror's proposal will describe in detail what they plan to accomplish and how they plan to satisfy all of the critical specifications at some point in time. For example: Air Worthiness is a critical specification to plan towards, but accomplishing the certification would happen much later. Explaining how you would work towards that end goal would be important, even if it isn't achievable at the end of this initial period of performance.

3.2.2 Preparation of the Technical Proposal

In accordance with the MTEC PPG, the technical proposal has a maximum limit of 30 pages and must include the following information:

1. **Prototype Design:** Describe the prototype design.
2. **Plan for Prototype Development:** Discuss the key points of a plan appropriate for the Offeror's stage of development.
3. **Key Deliverable(s) at End of 12 months:** State the deliverable of the project at the end of the first 12 months of the period of performance.
4. **Key Deliverables Beyond Year 1:** If funding was made available to continue your project beyond 12 months, state the proposed key deliverables to the best of your ability for Years 2-5.
5. **IP:** Describe pertinent information about Intellectual Property

6. **Anticipated Regulatory Pathway:** A description and justification of the anticipated regulatory pathway and current status in the U.S. and/or other countries, including completed and/or planned regulatory milestones.
7. **Status to Date:** Describe pertinent preliminary data and the status of the effort to date.
8. **Timeline/Cost:** Estimate the product development timeline and costs through product deployment/launch
9. **Cost per Unit:** Estimate the cost per unit
10. **Potential Commercialization Approach(es):** Discuss the commercial plans and manufacturing capability (including potential funding and resources) showing how the product will progress to the next phase and/or delivery to the market after the successful completion of this award
11. **Personnel:** Briefly state the qualifications of the PI and key personnel to perform the work.
12. **Previous Government Funding:** Include a listing of prior government awards supporting the prototype (if any).

Submitters should also include:

- Appendix A: Statement of Work (SOW) which includes proposed work and milestones
- Appendix B: Cost Proposal Narrative

The government may request additional information from potential offerors to verify information provided in the technical proposals.

3.2.3 Restrictions on Human Subjects, Cadavers, and Laboratory Animal Use

Technical proposals must comply with important restrictions and reporting requirements for the use of human subjects, to include research involving the secondary use of human biospecimens and/or human data, human cadavers, or laboratory animals. For a complete description of these mandatory requirements and restrictions and others, Offerors must refer to the accompanying MTEC PPG, Section 6.11 Additional Requirements.

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 USAMRMC Office of Animal Care and Use Office (ACURO) provides authorization that the research may proceed. The USAMRMC ACURO will issue written approval to begin research under separate notification. Written approval to proceed from the USAMRMC ACURO is also required for any Research Project Awardee (or lower tier subawards) that will use funds from this award to conduct research involving animal subjects. Offerors must allow at least 30 days in their schedule for the ACURO review and authorization process.

3.3 Cost Proposal

MTEC will make cost proposal formats available on the Members-Only MTEC website. **The proposal formats provided in the MTEC PPG is mandatory.** Refer to the MTEC PPG for additional details.

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.

3.3.1 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

As described in Section 3.3.2 of the Proposal Preparation Guide, the CM will conduct a preliminary screening of received proposals to ensure compliance with the RPP requirements. As part of the preliminary screening process, proposals that do not meet the requirements of the RPP may be eliminated from the competition or additional information may be requested. One of the primary reasons for non-compliance and elimination during this initial screening is that the proposal does not offer significant nontraditional defense contractor participation or cost share (see RPP Section 1.6). The Cost Sharing/Non-traditional Contractor determination will be made as shown in Table 1:

TABLE 1- COST SHARING/NON-TRADITIONAL 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 • Offeror's proposal has at least one Non-traditional Defense Contractor participating to a significant extent • Offeror provides at least one third of the total project cost as acceptable cost share
FAIL	Offeror proposing an MTEC research project does NOT meet any of the following: <ul style="list-style-type: none"> • Offeror is a Nontraditional Defense Contractor • Offeror's proposal has at least one Nontraditional Defense Contractor participating to a significant extent

	<ul style="list-style-type: none">• Offeror provides at least one third of the total project cost as acceptable cost share
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Following the preliminary screening, the Government sponsor 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) *Reject the proposal (will not be placed in the Basket)*

4.1 Proposal Evaluation Process

Qualified applications will be evaluated by a panel of subject matter experts that will make recommendations for funding to the Source Selection Authority appointed by the Commanding General, USAMRMC based on Factors, Sub-factors and criteria described below.

The RPP review and award process may involve the use of contractors as subject-matter-experts or reviewers; where appropriate, the USG will employ non-disclosure-agreements to protect information contained in the RPP as outlined in Section 1.4.

Evaluation of proposals offered in response to this RPP shall be based on an independent, comprehensive review and assessment against all source selection criteria and evaluation factors, as further described. A rating consistent with these evaluation factors will be derived from the ability of the Offeror to perform the work in accordance with all aspects of requirements outlined in this RPP. The Offeror shall clearly state how it intends to meet the requirements. Mere acknowledgement or restatement of a requirement or task is not acceptable.

Offerors submitting the best value proposals that meet the following Factors and evaluation criteria will be selected for award negotiations:

1. Technical Approach
2. Management, Schedule, Resources and Personnel
3. Potential for Transition and Commercialization
4. Cost/Price

Factors are listed in descending order of importance. The Technical Approach factor, Management, Schedule, Resources and Personnel factor, and Potential for Transition and Commercialization factor, when combined, are significantly more important than the Cost/Price factor; however, Cost/Price will contribute substantially to the selection decision. As the collective non-cost factors begin to reach equality in the technical evaluation ratings, cost becomes a more important factor in the trade off analysis.

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Table 2 explains the adjectival merit ratings that will be used for the non-cost factors.

TABLE 2- 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.

4.1.1 Factor 1. Technical Approach

(1) Ratings. The Technical Approach factor will be evaluated using the merit rating as shown in Table 2.

(2) Factor 1 Evaluation Process. The Offeror’s proposed solution will be assessed for the likelihood of successfully achieving the requirements of the technology of interest as defined in section 3.2 above. 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.

4.1.2 Factor 2. Management, Schedule, Resources and Personnel.

(1) Ratings. The Management, Schedule, Resources and Personnel factor will be evaluated using the merit rating as shown in Table 2.

(2) Factor 2 Evaluation Process. 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 minimum. This would include:
 - Any cost share proposed when it is not required by statute because your proposal includes a non-traditional defense contractor participating to a significant extent; or
 - Any cost share beyond the statutory 1/3 minimum requirement if your proposal does not include a non-traditional defense contractor.
- Detailed schedule with cost risks, and potential mitigation strategies identified.

4.1.3 Factor 3. Potential for Transition and Commercialization

(1) Ratings. The Potential for Transition and Commercialization factor will be evaluated using the merit rating as shown in Table 2.

(2) Factor 3 Evaluation Process. 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 animal 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.

4.1.4. Factor 4. Cost/Price

(1) Ratings. The Cost area will receive a narrative rating to determine whether costs are realistic, reasonable, and complete.

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(2) Factor 4 Evaluation Process. The MTEC CM will evaluate the estimated cost proposed by the Offeror for performing all requirements outlined in this RPP and the MTEC PPG. Evaluation will include analysis of the proposed cost together with all supporting information. The Offeror's cost and rationale will be evaluated for realism, reasonableness, and completeness. 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.

Proposals will be evaluated using the understanding of cost realism, reasonableness and completeness as outlined below:

(i) Realism. Proposals will be evaluated to determine if Costs are realistic for the work to be performed, reflect a clear understanding of the requirements, and are consistent with the various elements of the Offeror's schedule proposal.

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. For more information on cost realism, please refer to the MTEC PPG.

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.

(ii) Reasonableness. The Offeror's cost proposal will be evaluated to determine if it is reasonable. For a price to be reasonable, it must represent a price to the government that a prudent person would pay in the conduct of competitive business. Normally, price reasonableness is established through cost and price analysis.

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.

Costs provided shall be clearly attributable to activities or materials as described by the Offeror. Costs should be broken down using the Cost Proposal Formats that are located on the Members-Only MTEC website.

(iii) Completeness. The MTEC CM will evaluate whether the proposal clearly and thoroughly documents the rationale supporting the proposed cost and is compliant with the requirements of the solicitation.

The proposal should clearly and thoroughly document the cost/price information supporting the proposed cost in sufficient detail and depth. The MTEC CM will evaluate whether the Offeror's cost proposal is complete with respect to the work proposed. The MTEC CM will consider substantiation of proposed cost (i.e., supporting data and estimating rationale) for all elements.

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.

4.2 Best Value

The Government will conduct the source selection and MTEC CM will award the projects in Best Value sequence. 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 request changes to any or all parts of the SOW. Offeror's will have the opportunity to concur with the requested changes and revise cost proposals as necessary.

Definition of General Terms Used in Evaluations:

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

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 Manager, Ms. Lisa Fisher, lisa.fisher@ati.org
- Technical related questions should be directed to the MTEC Director of Research, Dr. Lauren Palestrini, Ph.D., lauren.palestrini@officer.mtec-sc.org
- Questions concerning membership should be directed to Ms. Stacey Lindbergh, MTEC Executive Director., execdirect@officer.mtec-sc.org.
- All other questions should be directed to Ms. Polly Graham, MTEC Program Manager, polly.graham@ati.org

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

6 Acronyms/Abbreviations

ACURO	Animal Care and Use Office
ATI	Advanced Technology International
CM	Consortium Manager
CMA	Consortium Member Agreement
CO2	Carbon Dioxide
DHP	Defense Health Program
DoD	Department of Defense
ECMO	Extracorporeal Membrane Oxygenation
FAQ	Frequently Asked Questions
F&A	Facilities and Administrative Costs
FDA	Food and Drug Administration
FY	Fiscal Year
G&A	General and Administrative Expenses
IP	Intellectual Property (e.g., patents, copyrights, licensing, etc.)
M	Millions
MTEC	Medical Technology Enterprise Consortium
NDA	Nondisclosure Agreement
OCI	Organizational Conflict of Interest
ODC	Other Direct Charges
OTA	Other Transaction Agreement
PMO-MD	Project Management Office, Medical Devices
POC	Point-of-Contact
PPG	Proposal Preparation Guide
PUL	Proposal Update Letter
RDT&E	Army Research, Development, Test and Evaluation
RPP	Request for Project Proposals
SOW	Statement of Work
USAARL	U.S. Army Aeromedical Research Laboratory
USAMMA	U.S. Army Medical Materiel Agency
USAMRMC	U.S. Army Medical Research and Materiel Command
USG	U.S. Government