Request for Project Proposals

Solicitation Number: MTEC-19-05-AntiScar
"Anti-Scar Treatment for Deep Partial-Thickness (DPT) Burns"

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: January 15, 2019
Amendment No. 01 Issue Date: February 6, 2019

Solutions Brief Due Date: February 28, 2019
Noon Eastern Time

Amendment No. 01 changes Section 1.2 (Purpose) on page 4, Section 2.2 (Funding Availability) on page 4 and Section 5 (Technical Requirements) on pages 11-13 are shown in red text. No other changes have been made.

White Papers Are NOT Required

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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 Materiel Command (USAMRMC) 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.

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 Dental and Craniofacial Trauma Research and Tissue Regeneration Directorate, U.S. Army Institute of Surgical Research (USAISR). 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 Dr. Kai Leung at the USAISR.

Overall end goal of program: The goal of this program is to develop a pharmacotherapy (i.e., drug treatment) for the acute management and prophylactic treatment of deep partial-thickness (DPT) burn wounds that is conducive to operations in combat theatre as well as fixed medical facilities. The Government seeks to rapidly advance the development of prototype drug therapy treatment(s) to U.S. Food and Drug Administration (FDA) approval for use in DPT burn-injured patients to enhance recovery, improve outcomes, and limit scarring.

Background: The current standard of care for DPT-burn injury remains supportive in nature, based on management of symptoms, with no prophylactic and drug therapies that address the scarring. Despite numerous clinical trials on potential therapies, no drug is approved by the FDA

for the prophylaxis or treatment of wound scarring. DPT-burn injury is associated with significant long-term morbidity requiring costly corrective surgeries. Up to $7.5 billion is spent annually on treatment of burns in the United States, and much of this cost is related to treatment of the resulting scar and contracture (Marshall et al., 2018, PMID: 29392092}. Therefore, it is important to develop a therapy that will mitigate the life-long disability and rehabilitation costs associated with these post-injury conditions.

Objective of RPP: The USAISR has developed a novel anti-scarring therapy and demonstrated proof-of-concept in mouse and swine models of DPT thermal burn. This RPP is seeking a team to continue the development of this anti-scarring therapy through the completion of clinical trial.

1.3. Proposers Conference

MTEC will host a Proposers Conference tentatively scheduled for 1 week after the release of the RPP that will be conducted via webinar. Further instructions will be forthcoming via email.

2. Administrative Overview

2.1. Request for Project Proposals (RPP)

Each MTEC Solution Brief submitted 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 DoD reserves the right to award Solution Briefs received from this RPP on a follow-on prototype Other Transaction Agreement (pOTA) or other stand-alone OTAs as necessary to meet mission requirements.

2.2. Funding Availability and Type of Funding Instrument Issued

The U.S. Department of Defense (DoD) currently has available approximately $2.4 Million (M) RDT&E funds for this effort. The U.S. Government may apply additional dollars for follow-on efforts with the evaluation and acceptance of work and cost plan with appropriate contract modification. A period of performance for Task 1 of up to 2 years is allowable.

It is expected that MTEC will make a single award to a qualified team to accomplish all tasks. If a single Solution Brief is unable to sufficiently address the entire scope of this RPP's technical objectives, several Offerors may be asked to work together in a collaborative manner as a single project team or MTEC may make multiple, individual awards to Performers(s) to accomplish subset(s) of the key tasks.

Any potential follow-on funding would be negotiated based on outcomes, cost sharing, partner matching and estimates for additional study completion.

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 Solution Briefs 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 and Deliverables.

The DoD-selected Awards will be funded under the prototype Other Transaction Agreement (pOTA) 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 pOTA between the DoD and MTEC. Subsequently, any Solution Brief that is selected for award will be funded through an Award issued under the Base Agreement. A sample of the MTEC Base Agreement can be found on the MTEC website at:
https://mtec-sc.org/wp-content/uploads/2018/04/MTEC_Base_Agreement_Final_Rev04.pdf

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 as well as clarifications found in Frequently Asked Questions (FAQ) responses.

2.3. Proprietary Information

The MTEC CM will oversee submission of Solution Briefs and Cost Proposals and analyze Cost 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 Solution Brief and Cost Proposal and the subsequent agreement administration if the Solution Brief and Cost Proposal is selected for award. An Offeror's submission of a Solution Brief and Cost 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, 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 (e.g., Bill and Melinda Gates Foundation) may be interested in reviewing certain Solution Briefs and Cost Proposals within their program areas, allowing opportunities to attract supplemental funding sources. On your Solution Brief and Cost Proposal Cover Page, please indicate your willingness to allow MTEC Officers and Directors access to your Solution Briefs and Cost Proposals for the purposes of engaging in outreach activities with these

private foundations. MTEC Officers and Directors granted 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 Solution Briefs or receive any research project funding through MTEC. Additionally, all DoD Evaluation Panel participants will agree to, and sign a nonproprietary information and conflict of interest document.

2.4. 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 **February 25, 2019**.

2.5. Inclusion of Nontraditional Defense Contractors or Nonprofit Research Institutions

Proposals that do not include Nontraditional Defense Contractor or Nonprofit Research Institution 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) for additional details.

2.6. 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.

2.7. Requirements

If the Offeror asserts either

(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 must 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 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 or nonprofit research institution's participation must 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 contribution* includes:

1. Supplying a key technology or products
2. Accomplishing a significant amount of the effort
3. Use of unique skilled personnel, facilities and/or equipment
4. Causing a material reduction in cost or schedule, and/or improvement in performance

2.8. 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; 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 DoD-Performer collaboration.

Cash Contribution

Cash Contribution means the Consortium and/or the Awardee (or Awardees' lower tier subawards) financial resources expended to complete the SOW. The cash contribution may be derived from the Consortium's or 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 SOW or specific tasks identified within the SOW. 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, 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 the SOW 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, intellectual property (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 Solution Brief contains multiple team members, this information shall be provided for each team member providing cost share.

2.9. 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 award is executed. Awardees are not allowed to use MTEC funding to pay for their assessment fees.

2.10. Intellectual Property

Intellectual Property (IP) rights for MTEC 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 DoD and the individual Performers during the entire award period.

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 Awards:

- **Royalty Payment Agreements**
  DoD-funded awards through MTEC will be subject to a 10% royalty on all Net Revenues received by the Award recipient resulting from the licensing/commercialization of the technology, capped at 200% of the DoD funding provided.
- **Additional Research Project Award Assessment**
  In lieu of providing the royalty payment agreement described above, members receiving 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 awards, whether the award is DoD funded or privately funded.

2.11. 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 DoD with DoD purpose data rights or unlimited data rights. If this is not the intent, then the Solution Brief should discuss data rights associated with each item**, and

possible approaches for the DoD to gain DoD purpose data rights or unlimited data rights as referenced in the Base Agreement. Rights in technical data in each Award shall be determined in accordance with the provisions of MTEC Base Agreement.

2.12. Expected Award Date

Offeror should plan on a period of performance (POP) that commences on August 1, 2019 (subject to change)**.** The DoD reserves the right to change the proposed period of performance start date through negotiations via the CM and prior to issuing a Research Project ward.

2.13. 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 successful will move forward to the next phase of solution brief pitch while those rejected will gain evaluation rationale for non-selection.

3. Solution Brief

3.1. Solution Brief

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 may not be evaluated.

3.2. Solution Brief Submission

Instructions on how to submit are included in the RPP version that is posted on MTEC Members Only Site.

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

3.3. 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.

MTEC will email receipt confirmations to Offerors upon submission. Offerors may submit in advance of the deadline. **Neither MTEC nor ATI will make allowances/exceptions for submission problems encountered by the Offeror using system-to-system interfaces with MTEC's submission form. If the Offeror receives errors and fails to upload the full submission prior to the submission deadline, the submission will not be accepted.**

4. Solution Brief Preparation Instructions

4.1. General Instructions

The Solution Brief format provided in this MTEC RPP is mandatory and shall reference this RPP number (MTEC-19-05-AntiScar). 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

Background/Status of the Anti-Scarring Drug Prototype Developed by the USAISR:

The anti-scar drug developed by the USAISR is pirfenidone (Pf), a small molecule with a molecular weight of 185 g/mol that belongs to the chemical class of pyridinone with a formal name of pyridine (5-methyl-1-phenyl-2(1H)-pyridinone. Pf is an FDA-approved antifibrotic drug for treating pulmonary fibrosis.[1] The USAISR repurposed Pf as a prophylactic agent and treatment primarily for DPT burn wounds, for reducing burn-induced hypertrophic scarring. Pf is safe and effective when administered orally at 2.4 grams per day for the treatment of pulmonary fibrosis.

The USAISR's studies of Pf treatment *in vitro* and *in vivo* demonstrated reduced inflammation and fibrosis, suggesting its potential usefulness as a prophylaxis and treatment for DPT and full-thickness (FT) burn wounds. Pf reduced the key inflammatory cytokines IL-1β, IL-2, IL-6, IL-13, and MIP-1α; decreased neutrophil infiltration in mouse DPT-burn wounds; reduced α-smooth muscle actin, and trended to reduce fibrosis without delayed epithelialization in mouse burn

[1] https://clinicaltrials.gov/ct2/results?term=pirfenidone+AND+fibrosis&Search=Search

wounds.[2,3] *In vitro*, Pf inhibited human dermal fibroblasts (HDF) transdifferentiation to myofibroblasts; weakened the contractile machinery of activated dermal myofibroblasts; decreased collagen deposition and fibrosis-related gene expression; and, reduced p38 MAPK activation in HDF stimulated with TGF-β1.[4]

The Government is seeking to accomplish the strategizing, planning, and implementation of manufacturing, IND-enabling studies, and early phase clinical trials of an anti-scarring drug prototype. The Government expects that the Awardee shall conduct focused research that results in early clinical trial(s) of the anti-scar drug therapy prototype described above. The Awardee's team shall be led by a centralized point of contact that integrates multiple partners and the Government Steering Committee (GSC) in a comprehensive strategy for accomplishing the work. Infrastructure shall not require funding for standup.

The end-goal of the work funded by this RPP is the completion of a Phase 0/1 clinical trial. Offerors should propose against the following technical needs and are encouraged to bring partnerships to their proposals to meet these needs. Offerors are also encouraged to submit proposals that may respond to some, but not all, of the needs listed below. The Government reserves the right to facilitate partnering among several proposals to form a team that can execute all of the requirements specified herein.

1) Technical need for expertise in selecting dosage formulation (e.g., emulsion, film) and manufacturing of topical drug products; IND-enabling studies, including strategy, planning, and execution; chemistry, manufacturing, and control (CMC); and clinical strategy and protocol development and implementation of early clinical trials (Phase 0 and/or Phase 1) for wound healing treatments, including patient recruitment, clinical trial data management, interactions with FDA for regulatory compliance — for assessing safety, tolerability, and potential efficacy.
2) Existing clinical trial centers with a proven history of burn-wound patient recruitment and integration of Contract Resource Organization, with infrastructure already in place with no funding needed for standup.
3) Team of subject matter experts that shall produce and design standardized, exploratory and adaptive studies to answer, dose, duration of treatment, pharmacokinetics (PK), and pharmacodynamics (PD) status of the drug prototype(s) in wound-injured subjects.

[2] Medina, J.L., E.A. Sebastian, A.B. Fourcaudot, R. Dorati, and K.P. Leung, *Pirfenidone Ointment Modulates the Burn Wound Bed in C57BL/6 Mice by Suppressing Inflammatory Responses.* Inflammation, 2018. In Press.
[3] Dorati, R., J.L. Medina, P.P. DeLuca, and K.P. Leung, *Development of a Topical 48-H Release Formulation as an Anti-scarring Treatment for Deep Partial-Thickness Burns.* AAPS PharmSciTech, 2018. 19(5):2264-2275.
[4] Hall, C.L., A.R. Wells, and K.P. Leung, *Pirfenidone reduces profibrotic responses in human dermal myofibroblasts, in vitro.* Lab Invest, 2018. **98**(5): p. 640-655.

4) Determine evaluation criteria and strategy (cost, schedule, feasibility, pre-clinical data analysis, etc.) for the entire advanced development after dose-ranging animal studies and up to and including Phase 0, 1, and/or Phase 2 clinical trials.
5) Determine and defend study design concepts for anti-scar drugs including type of wounds and dosage, methods for analysis, and population enrichment.
6) Describe and determine criteria for moving promising anti-scar drug therapy prototypes further into advanced development.
7) Determine strategy and manage relationships among partners including non-disclosure agreements, intellectual property rights, regulatory sponsorship and strategy, indications for use, anticipated or known side effects with current standard of care for wounds, and regulatory milestones for FDA approval.
8) Determine evaluation criteria and strategy for anti-scar treatment manufacturing timeline and costs, methods to ensure Good Manufacturing Processes, product quality assurance and testing, strategy for initial manufacturing lots for clinical trial testing, long term manufacturing and sustainment.

The full spectrum of work is expected to be conducted in several tasks. Task 1 is the basis for the initial award but Tasks 2 and 3 may be added as follow-on work dependent on the technical progress and/or outcome of Task 1, and therefore, may be of interest to potential Offerors. **Potential Offerors are expected to propose in response to Tasks 1 and 2 only, and should include a ROM for both Task 1 and Task 2 (i.e., a ROM for Task 1 and a separate ROM for Task 2). [NOTE: If your Solution Brief is invited for a Solution Brief Pitch, then you will be expected to provide a detailed cost proposal for Task 1 only.]**

Task 1 (PoP up to 2 years): Execute all preclinical work required to prepare for early clinical trials for wound healing treatments. Task 1 is expected to be completed within two (2) years. Interactions with the FDA are highly encouraged within Task 1 so that all IND-enabling studies and clinical planning are executed in alignment with FDA expectations. Anticipated Task 1 activities include (but are not limited to):

- Select dosage and formulation (e.g., emulsion, film);
- Manufacture (cGMP) of topical drug products;
- IND-enabling studies, including strategy, planning, and execution; chemistry, manufacturing, and control (CMC);
- Clinical strategy and protocol development of early clinical trials (Phase 0 and/or Phase 1); and
- Execution of a pre-IND meeting with the U.S. FDA.

Potential Follow-on Task 2: Conduct an FDA-compliant early clinical trial (Phase 0 and/or Phase 1) for wound healing treatments. Anticipated Task 2 activities include (but are not limited to):

- Conception and execution of appropriate regulatory strategy (e.g., submission of Investigational New Drug [IND] application and other FDA-compliant responsibilities);
- Conduct of Phase 0 / 1 clinical trial as the regulatory sponsor (accordingly, the development partner bears the legal responsibilities of sponsor under 21 CFR 312 Subpart D);
- Establishment and management of clinical trial sites;
- Recruitment, enrollment, and clinical monitoring at all enrollment sites; and
- Provisions of all aspects of data configuration, data management, analysis, and reporting in compliance with all applicable regulatory guidance and Code of Federal Regulations (CFRs).

Further negotiations will be conducted between the Awardee, MTEC, and the Government if proceeding to a Phase 1 clinical trial becomes feasible.

Potential Follow-on Task 3: If the Phase 0/1 clinical trial is successful, then the Awardee may be offered an optional extension to conduct a Phase 2 clinical trial. Further negotiations will be conducted between the Awardee, MTEC, and the Government if proceeding to a Phase 2 clinical trial becomes feasible.

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 clinical studies under this RPP shall not begin until the USAMRMC Office of Research Protections (ORP) provides authorization that the research may proceed. The USAMRMC ORP will issue written approval to begin research under separate notification. Written approval to proceed from the USAMRMC ORP is also required for any Research Project Awardee (or lower tier subawards) that will use funds from this award to conduct research involving

human subjects. Offerors must allow at least 60 days in their schedule for the ORP 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 will 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:

- **Title Page** (excluded from the 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-19-05-AntiScar"
  - 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 Solution Brief for the purposes of engaging in outreach activities with these private sector entities. MTEC staff has signed NDAs and OCI statements.]

- **Approach:** [Briefly describe your approach to solving the problem. Include relevant background data about your approach.]

- **Objectives:** [Specify the objectives of the proposed effort.]

- **Technical Strategy**: [Outline the proposed methodology by Task in sufficient detail to show a clear course of action that addresses the technical requirements described in this RPP. This section should identify any pilot or existing commercial methodology/technology or the development of such during the course of the work. If novel technology or methods are to be employed, then identify the path to maturation.]

- **Anticipated Outcomes**: [Provide a description of the anticipated outcomes from the proposed work. List milestones and deliverables from the proposed work.]

- **Experience:** [The Solution Brief shall describe the experience of the Principal Investigator, key personnel, partner organizations, and associated subject matters experts that are required to meet the program's objective and requirements. Identify any work of a similar nature that could be used to gauge the effectiveness and worthiness of the technical or methodological approach. This section should not highlight the contractual details of relevant experience, but should emphasize past work that is relevant and similar in nature (complexity, size, requirements) to this request and how that work's outcome relates to the expectations set forth in this RPP. Offerors should indicate how much of this relevant experience and past effort they will leverage for the proposed effort. Offeror may choose format and method of conveying this.]

- **Timeline:** [Indicate the total proposed delivery schedule. Provide an estimated Gantt Chart of the major activities proposed.]

- **Project Management Plan:** [The Solution Brief shall describe the overall project management plan.]

- **Data Rights:** [If applicable, complete the below table for any items to be furnished to the DoD with restrictions. An example is provided below.]

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	DoD Purpose Rights	Organization XYZ	Milestone 2

- **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 2.5-2.8 for more information.]

- **Rough Order of Magnitude (ROM) Pricing:** [Refer to Attachment B].

The Solution Brief is limited to ten (10) pages (excluding cover page), 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 page limit will not be accepted.**

MTEC will email receipt confirmations to Offerors upon submission of Solution Briefs. Offerors may submit Solutions Briefs in advance of the deadline.

Solution Brief Evaluation:

The CM will distribute all Solution Briefs to the Government for evaluation. Solution Briefs will be evaluated based on the following criteria:

- **Research Strategy:**
    - Whether the proposed work supports the objectives of USAISR. How well the research will address a healthcare issue relevant to military Service members.
    - How well the specific aims and proposed methodology support the technical objectives and the development of the prototype.
    - How well the Solution Brief defines a prototype that meets the requirements set forth in this RPP. Whether the prototype is based on promising preliminary data, sound scientific rationale, and demonstrated proof-of-concept.

- **Personnel and Team:**
    - How the background and expertise of the personnel and organizations are appropriate to accomplish the proposed research.
    - Ability to execute the research.

Upon review of the Solution Briefs, Offerors may be invited into Step 2 of the Solution Brief process. Offerors who are not invited to proceed into Step 2 will be provided feedback.

Step 2: Solution Brief Pitch:

In Step 2, the Offeror(s) will provide a virtual or in-person "pitch" of the proposed project along with a SOW/Milestone Payment Schedule (MPS) and ROM Pricing (see Attachment A) 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 Phase 1. Specifically, the pitch should include the following:

- **Description:** The Offeror will provide a more robust description of their approach and emphasize why this approach is expected to result in a successful outcome. This approach should follow the SOW/MPS provided with the pitch.

- **Progress:** The Offeror will 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.

- **Relevant Experience:** The Offeror will 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.

- **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.

- **Data Rights Assertions:** The Solution Brief will identify any and all proprietary and/or intellectual property involved in the efforts and any associated restrictions that may possibly affect the Government's use of the property in any way whatsoever. Offeror

must describe pathway to developing this into a product that can be used by the DoD and other potential customers (if applicable). Include relevant information about existing royalty agreements. See Section 1.10 for format.

- **Cost:** The Solution Brief Pitch must present summarized costs at the task level.

- **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. See Attachment A for additional information.

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:

- Most Important (of equal importance)
    - Performance: Overall technical approach and how well Offeror's solution enhances the DoD mission described in the RPP; including processes described to identify and manage risks/opportunities
    - Schedule: Suitability of the notional schedule, including processes described to identify and manage risks/opportunities.
    - Cost: The parity of the relationship between the Offeror's solution and ROM costs, and whether a superior technical approach is warranted at a higher estimated cost.
    - Risk-Opportunity: Identification of risks (with supportable mitigations) and opportunities with the Offeror's approach with objective measurable metrics.
    - Inclusion of nontraditional or small business participation, a nonprofit research organization, **or** 1/3 cost share.
- Less Important (of equal importance)
    - Relevant Experience.

- Assessment of the potential impact of data rights assertions.

At the conclusion of the Step 2 evaluation, Offerors who are favorably evaluated 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.

Step 3: Cost Proposal

The Offerors invited to submit a Cost Proposal are encouraged to contact the MTEC and/or Government with any questions so that all aspects are clearly understood by both parties. The full proposal should include the following and be completed in accordance with Section 3 of this RPP and 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.

6.2. Cost Proposal

Offerors are encouraged to use their own cost formats such that the necessary cost detail is provided. Cost Proposals should be broken out by task. MTEC will make cost proposal formats available on the Members-Only MTEC website. 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.

6.3. 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 to ensure compliance with the RPP requirements. The Government reserves the right to request additional information

or eliminate solution briefs that do not meet these requirements from further consideration. One of the primary reasons for elimination from further consideration is the lack of significant nontraditional defense contractor participation, nonprofit research institution participation, all small business participation, or cost share (see RPP Section 2.6). The Cost Sharing/Nontraditional Contractor determination will be made as shown in Table 1:

TABLE 1- COST SHARING/NONTRADITIONAL CONTRACTOR ASSESSMENTS	
RATING	**DESCRIPTION**
PASS	Offeror proposing an MTEC research project meets at least ONE of the following: • 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 • 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: • Offeror is a Nontraditional Defense Contractor or Nonprofit Research Institution • Offeror's Solution Brief has at least one Nontraditional Defense Contractor or Nonprofit Research Institution participating to a significant extent • 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 or not selected.

The RPP review and award process may involve the use of contractors as subject-matter-experts or reviewers; where appropriate, the U.S. Government (USG) will employ NDAs to protect information contained in the RPP as outlined in Section 2.3.

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, Ms. Rebecca Harmon, mtec-contracts@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. Kathy Zolman, MTEC Program Manager, kathy.zolman@ati.org

Once an Offeror has submitted a Solution Brief, the DoD 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
CM	Consortium Manager
CMA	Consortium Member Agreement
CMC	Chemistry, manufacturing, and control
DHA	Defense Health Agency
DHP	Defense Health Program
DoD	Department of Defense
DPT	Deep partial thickness
FAQ	Frequently Asked Questions
F&A	Facilities and Administrative Costs
FDA	U.S. Food and Drug Administration
FT	Full thickness
FY	Fiscal Year
G&A	General and Administrative Expenses
GSC	Government Steering Committee
HDF	Human dermal fibroblasts
HRPO	Human Research Protections Office
IACUC	Institutional Animal Care and Use Committee
IND	Investigational New Drug
IP	Intellectual Property (e.g., patents, copyrights, licensing, etc.)
IRB	Institutional Review Board
IR&D	Independent Research and Development
M	Millions
MPS	Milestone Payment Schedule
MTEC	Medical Technology Enterprise Consortium
NDA	Nondisclosure Agreement

OASDHA	Office of the Assistant Secretary of Defense for Health Affairs
OCI	Organizational Conflict of Interest
ODC	Other Direct Charges
ORP	Office of Research Protections, USAMRMC
POC	Point-of-Contact
PAR	Patient at Risk
PD	Pharmacodynamics
Pf	Pirfenidone
PK	Pharmacokinetics
POP	Period of performance
pOTA	Prototype Other Transaction Agreement
PPG	Proposal Preparation Guide
RDA	Research, Development, and Acquisition
RDT&E	Research, Development, Test, and Evaluation
ROM	Rough Order of Magnitude
RPP	Request for Project Proposals
SOW	Statement of Work
USAISR	U.S. Army Institute of Surgical Research
USAMRMC	U.S. Army Medical Research and Materiel Command
USG	U.S. Government, specifically the DoD

Attachment A: Statement of Work (SOW)

The SOW developed by the Lead MTEC member organization and included in the proposal (also submitted as a separate document) is intended to be incorporated into a binding agreement if the proposal is selected for award. If no SOW is submitted with the proposal, there may 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 proposal submission. Submitted information is subject to change through negotiation if the Government selects the proposal for funding.)*

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

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

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

State the technology objective 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 proposal submission. Submitted information is subject to change through negotiation if the Government selects the proposal 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 proposal submission. Submitted information is subject to change through negotiation if the Government selects the proposal 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 25th of Apr, Jul, Oct, Jan), Annual Technical Report, Final Technical Report, and Final Business Status Report. Reports shall have no funding associated with them.

MTEC Milestone Payment Schedule Example

MTEC Milestone Number	Task Number	Significant Event/ Accomplishments	Due Date	Government Funds	Cost Share	Total Funding
1	N/A	Project Kickoff	12/1/2019	$20,000		$20,000
2	N/A	Quarterly Report 1 (October - December, Technical and Business Reports)	1/25/2020	$ -		$ -
3	1	Protocol Synopsis	2/28/2020	$21,075		$21,075
4	2	Submission for HRPO Approval	2/28/2020	$21,075		$21,075
5	3	Submission of Investigational New Drug application to the US FDA	4/30/2020	$210,757	$187,457	$398,214
6	N/A	Quarterly Reports 2 (January - March, Technical and Business Reports)	4/25/2020	$ -		$ -
7	N/A	Quarterly Report 3 (April - June, Technical and Business Reports)	7/25/2020	$ -		$ -
8	4	Toxicity Studies	10/1/2020	$63,227		$63,227
9	N/A	Annual Report 1	10/25/2020	$ -		$ -
10	5	FDA authorization trial	11/30/2020	$84,303		$84,303
11	6	Research staff trained	11/30/2020	$ -		$ -
12	7	Data Management system completed	11/30/2020	$ -		$ -
13	8	1st subject screened, randomized and enrolled in study	1/1/2021	$150,000	$187,457	$337,457
14	N/A	Quarterly Report 4 (October - December, Technical and Business Reports)	1/25/2021	$ -		$ -
15	9	Completion of dip molding apparatus	3/1/2021	$ 157,829	$ 187,457	$ 345,286
16	N/A	Quarterly Reports 5 (January - March,	4/25/2021	$ -		$ -

		Technical and Business Reports)				
17	10	Assess potential toxicology	6/1/2021	$157,829		$157,829
18	N/A	Quarterly Report 6 (April - June, Technical and Business Reports)	7/25/2021	$ -		$ -
19	11	Complete 50% patient enrollment	10/1/2021	$350,000	$187,457	$537,457
20	N/A	Annual Report 1	10/25/2021	$ -		$ -
21	N/A	Quarterly Report 7 (October - December, Technical and Business Reports)	1/25/2022	$ -		$ -
22	12	Electronic Report Forms Developed	3/1/2022	$315,658	$187,457	$503,115
23	N/A	Quarterly Reports 8 (January - March, Technical and Business Reports)	4/25/2022	$ -		$ -
24	N/A	Quarterly Report 9 (April - June, Technical and Business Reports)	7/25/2022	$ -		$ -
25	13	Complete 100% patient enrollment	8/1/2022	$315,658	$187,457	$503,115
26	N/A	Annual Report 1	10/25/2022	$ -		$ -
27	14	Report results from data analysis	11/1/2022	$157,829		$157,829
28	N/A	Final Reports **(Prior to the POP End)**	11/30/2022	$ -		$ -
			Total	**$2,025,240**	**$1,124,742**	**$3,149,982**

Please Note:

1. Firm Fixed Price Contracts – Milestone must be complete before invoicing for fixed priced contracts.

2. Cost Reimbursable Contracts – You may invoice for costs incurred against a milestone. Invoicing should be monthly.

3. Cannot receive payment for a report (i.e. Quarterly, Annual and Final Reports should not have an assigned Government Funded or Cost Share amount.)

4. Quarterly and Annual Reports include BOTH Technical and Business Reports (separate).

5. Final Report due date must be prior to POP end noted in subcontract.

6. MTEC Milestone Numbers are used for administrative purposes and should be sequential.

7. Task Numbers are used to reference the statement of work if they are different from the MTEC Milestone Number.

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

Data Rights *(see Section 8.4 of PPG for more information)*

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

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

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

- Quarterly Reports – The MTEC research project awardee shall prepare 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 prepare 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)

Attachment B: Rough Order of Magnitude (ROM) Pricing

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 ROM.** 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.

Labor	*$ 100,000.00*
Labor Hours	*1,000.0 hrs*
Subcontractors	*$ 50,000.00*
Subcontractors Hours	*500.0 hrs*
Consultants	*$ 10,000.00*
Consultants Hours	*100.0 hrs*
Material/Equipment	*$ 75,000.00*
Other Direct Costs	*$ 1,000.00*
Travel	*$ 5,000.00*
Indirect costs	*$ 48,200.00*
Total Cost	*$ 289,200.00*
Fee (*Not applicable if cost share is proposed)*	*$ 0.00*
Total Cost (plus Fee)	*$ 289,200.00*
Cost Share **(if cost share is proposed then fee is unallowable)**	*$ 290,000.00*
Total Project Cost	*$ 579,200.00*