Request for Project Proposals

Solicitation Number: MTEC-18-02-OpticNerve
"Prototype Solutions for Optic Nerve Injury"

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

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Noon Eastern Time

White Papers are Required

Table of Contents

1 Request for Project Proposal Overview

1.1 Purpose

The Medical Technology Enterprise Consortium (MTEC) is an enterprise partnership that collaborates 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) development 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, "nontraditional" government contractors, academic research institutions and not-for-profit organizations. For more information on the MTEC mission, see the MTEC website https://mtec-sc.org/.

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 USAMRMC Clinical and Rehabilitative Medicine technology objective. Strategic oversight for the award(s) supported by this RPP will be provided by USAMRMC.

MTEC operates under a prototype Other Transaction Agreement (pOTA) with USAMRMC. Proposed prototype projects should not be exploratory in nature and do require a foundation of preliminary data. As defined in the OTA Guide dated January 2017, a prototype project can generally be described as a preliminary pilot, test, evaluation, demonstration, or agile development activity used to evaluate the technical or manufacturing feasibility or military utility of a particular technology, process, concept, end item, effect, or other discrete feature. Prototype projects may include systems, subsystems, components, materials, methodology, technology, or processes. By way of illustration, a prototype project may involve: a proof of concept; a pilot; a novel application of commercial technologies for defense purposes; a creation, design, development, demonstration of technical or operational utility; or combinations of the foregoing, related to a prototype. The quantity should generally be limited to that needed to prove technical or manufacturing feasibility or evaluate military utility.

1.2 Background

Funds from the Defense Health Program (DHP) Research, Development, Test, and Evaluation (RDT&E) appropriation are being made available to advance the state-of-the-art in biomedical manufacturing. Specifically, funds are to support areas of regenerative medicine that require development and harmonization into reproducible, consistent procedures which could stand the test of U.S. Food and Drug Administration (FDA) approval. **This MTEC RPP focuses on biomanufacturing and/or development of a device, biologic, or combination prototype that aims to maintain, re-establish or regenerate damaged visual pathways. Applications to MTEC should clearly state how the proposed research provides an innovative solution to a critical problem in visual loss.**

In order to qualify for an award under this RPP, the project must fall within the prescribed areas of military need outlined in Section 2 and have a component of the project that involves prototype development and/or manufacturing (e.g., scale up and standardization). It is expected that many of the actual regenerative medicine projects may still be at the academic level, yet the manufacturing requirements demanded are most suited to industry. MTEC, therefore, considers that a teamed approach may have the greatest level of success, especially considering that the eventual goal is to transition products to industry for FDA approval.

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

1.3 Acquisition Approach

This RPP will be conducted using a two-staged approach. In Stage 1, current MTEC members are invited to submit White Papers using the format contained in this RPP (Attachment 1). The Sponsors (i.e., USAMRMC, Glaucoma Research Foundation, and BrightFocus Foundation) will evaluate White Papers submitted and will select White Papers that best meet their current technology priorities using the criteria in Section 3. Offerors whose technology solution is selected for further consideration based on White Paper evaluation will be invited to submit a proposal in Stage 2. Notification letters will contain specific Stage 2 proposal submission requirements. Stage 2 proposals will be evaluated using a two-tier review process, consisting of scientific peer review and programmatic review, to ensure both scientific excellence and programmatic relevance.

1.4 Military Relevance and Dual-Use

Military relevance is a critical component of proposal submission. The Clinical and Rehabilitative Medicine Research Program (CRMRP) focuses on innovations to reconstruct, rehabilitate, and provide definitive care for injured Service members. The ultimate goal is to return the Service members to duty and restore their quality of life. Innovations developed from CRMRP-supported research efforts are expected to improve restorative treatments and rehabilitative care to maximize function for return to duty (RTD) or civilian life. The CRMRP interest is in medical technologies (drugs, biologics, and devices) and treatment/rehabilitation strategies (methods, guidelines, standards, and information) that will significantly improve the medical care provided to our wounded Service members within the DoD health care system. Implementation of these technologies and strategies should improve the following: the rate of RTD of Service members, the time to RTD, clinical outcome measures, quality of life, as well as reduce the hospital stay lengths, clinical workload (patient encounters, treatments, etc.), and initial and long-term costs associated with restorative and rehabilitative or acute care.

The prototype development proposed in response to this RPP may also be intended and commercialized for dual-use in both military and civilian markets. The limited commercial viability of a product intended solely for the trauma market makes funding a product with potential 'dual use' for other more common applications attractive. Offerors are encouraged to describe the potential civilian markets relevant to their proposed prototype, for example, treatment of glaucoma or age-related macular degeneration.

1.5 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.

1.6 Request for White Papers and Process Stages

MTEC recognizes that considerable effort is required to prepare a competitive proposal to MTEC. The two-stage approach for this RPP is intended to streamline the initial proposal preparation time and effort for MTEC members. Based on the Government's evaluation of White Papers in Stage 1, select Offerors will be invited to participate in Stage 2 and will be required to submit a full proposal for more detailed evaluation.

The due date for White Papers is found on the cover page of this RPP. White Papers will not be considered under this RPP unless the White Paper was received on or before the due date specified on the cover page.

Stage 1: White Papers submitted under this RPP must follow the MTEC White Paper Template provided in Attachment 1.

Stage 2: Offerors whose technology solutions are selected for further consideration based on White Paper evaluation will be invited to submit a proposal in Stage 2. Notification letters will contain specific Stage 2 proposal submission requirements. An example of the proposal submission requirements is (subject to change):

- **Technical Proposal** according to the format provided in the Proposal Preparation Guidelines (PPG) available on the MTEC members-only website.
- Detailed **Statement of Work (SOW)** according to the format provided in the notification letter.
- **Cost Proposal** according to the format provided in the PPG.

1.7 Potential Funding Availability

The U.S. Government (USG) currently has available approximately $3 million (M) for Fiscal Year (FY) 2017. In addition, Glaucoma Research Foundation and BrightFocus Foundation supports vision research and are interested in co-funding vision projects up to $1.5M each for a potential of **$6M in total funding**. Under a Non-Disclosure Agreement (NDA), Glaucoma Research Foundation and BrightFocus Foundation will have access to white papers and proposals submitted through this RPP for the purposes of the evaluation and selection process.

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 one or two awards at $3.0M each (direct and indirect costs) will be made to qualified teams composed of teaming arrangements demonstrated to achieve advanced manufacturing[1] and/or prototype development.

The Period of Performance (POP) is not to exceed 36 months.

1.8 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

[1] "Advanced manufacturing" is a family of activities that (a) depend on the use and coordination of information, automation, computation, software, sensing, and networking, and/or (b) make use of cutting edge materials and emerging capabilities enabled by the physical and biological sciences, for example nanotechnology, chemistry, and biology (National Strategic Plan for Advanced Manufacturing, 2012).

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 White Paper Cover Page, please indicate your willingness to allow MTEC Officers, MTEC Staff, and Directors access to your Technical Proposal for the purposes of engaging in outreach activities with these private foundations. MTEC Officers and Staff who are granted proposal access have signed Nondisclosure Agreements (NDAs) and Organizational Conflict of Interest (OCI) statements. Additionally, these MTEC Officers, MTEC Staff, and Directors 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, which may include contractor support personnel, will agree to and sign a Federal Employee Participation Agreement or a Nondisclosure/Nonuse Agreement, as applicable.

1.9 Cost Sharing Definition

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.* 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 an 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 Government-contractor collaboration.

1.10 Cost Share Requirements

Research Projects selected for funding under this RPP are required to have at least one nontraditional defense contractor or nonprofit research institution participating to a significant extent. Projects that do not meet this requirement must provide at least 1/3 of the Research Project cost as cost share. Beyond that, cost sharing is encouraged if possible, as it leads to stronger leveraging of Government-contractor collaboration. More information regarding nontraditional defense contractor and nonprofit research institution requirements can be found at Attachment 2. For more information regarding cost share, please see Attachment 3.

1.11 White Paper Submission

White Papers shall be submitted by the date and time specified on the cover page using the submission form located here: https://secure.ati.org/mtec/whitepaperMTEC.html. Include the "MTEC-18-02-OpticNerve" Solicitation Number on each White Paper submitted.

MTEC membership is required for the submission of a White Paper.

Do not submit any classified information in the White Paper or proposal submission.

1.12 Submission Format

Found on the MTEC Members Only Site.

1.13 White Paper Preparation Cost

Found on the MTEC Members Only Site.

2 Technical Requirements

The overarching goal of this program is to provide biomanufacturing for an emerging area of medical technology and innovation to support standard procedures toward a device, biologic, or combination prototype to maintain, re-establish or regenerate damaged visual pathways. Applications to MTEC should clearly state how the proposed research provides an innovative solution to a critical problem in visual loss.

Applications must address one or more of the following focus areas in nerve regeneration or end-organ health. Specifically, MTEC seeks biomanufacturing and/or prototype development of a device, biologic, or combination prototype that supports:

1. Enhance optic nerve regeneration.
2. Re-establish neuronal connections between retinal ganglion cells and the lateral geniculate nucleus with high efficiency.

The current effort aims to promote highly innovative, groundbreaking research; high-impact research with near-term clinical relevance; multidisciplinary, synergistic research; and translational studies to support the fluid transfer of knowledge from basic principles to clinical solutions. Purely *in vitro* efforts will not be considered. Please note that awards are not to be exploratory in nature and require a foundation of preliminary data. Research involving animal or human subjects is allowed, in accordance with the PPG.

The expected period of performance should not exceed 36 months.

3 Selection/Evaluation Criteria

3.1 Stage 1: White Papers

3.1.1 Compliance Screening

The CM will conduct a preliminary screening of received White Papers to ensure compliance with the RPP requirements. As part of the preliminary screening process, White Papers that do not

meet the requirements of the RPP will be eliminated from the competition or additional information may be requested (at the discretion of the CM).

3.1.2 Selection Criteria

The Government will evaluate White Papers submitted under this RPP using the following criteria:

(1) **Programmatic Relevance:** Whether the proposed research idea supports the objectives of the USAMRMC. How well the research will address a healthcare issue relevant to military Service members, Veterans, and/or beneficiaries.

(2) **Prototype:** How well the pre-application defines a prototype (e.g., drug, device) that will address an unmet need. Whether the prototype is based on promising preclinical findings, sound scientific rationale, and demonstrated proof-of-concept.

(3) **Research Strategy:** How well the specific aims and proposed methodology support the research objectives and the development of the prototype.

(4) **Personnel:** How the background and expertise of the personnel are appropriate to accomplish the proposed research.

(5) **Impact:** Whether the potential immediate and long-range outcome(s)/product(s) (intellectual and/or materiel) of the proposed research, if successful, will impact a central critical problem or question in the field of research and/or patient care.

(6) **Administrative Compliance:** Plan to include significant participation of non-traditional contractor, nonprofit research institution, or a 1/3 cost share.

Under a Non-Disclosure Agreement (NDA), Glaucoma Research Foundation and BrightFocus Foundation will have access to white papers submitted through this RPP for the purposes of the evaluation and selection process. In addition to the aforementioned selection criteria, Glaucoma Research Foundation and BrightFocus Foundation will evaluate White Papers using the additional following criteria:

(7) **Dual-Use:** Whether the proposed research addresses a healthcare issue relevant to the civilian population, specifically glaucoma or age-related macular degeneration.

Those White Papers that are favorably evaluated will be invited to participate in Stage 2 for further consideration. Offerors whose White Papers were not favorably evaluated will be provided feedback on the evaluation.

3.2 Stage 2: Full Proposal Evaluation

To the maximum extent practicable, the evaluation criteria found in Attachment 4 are anticipated for Full Proposals.

4 Other Factors to Consider

Please note that MTEC members who are invited to participate in Stage 2 will be required to comply with the following requirements in addition to any Stage 2 proposal requirements:

1. If Offerors have not yet executed a MTEC Base Agreement, then Offerors must certify on the cover page of their full proposal that, if selected for award, they will abide by the terms and conditions of the latest version of the MTEC Base Agreement.
2. Warranties and Representations for all proposals - See Attachment 5.
3. MTEC Additional Research Project Award Assessment or Royalty Payment Agreement – See Attachment 6.

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, 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 White Paper, neither the Government nor the MTEC CM will discuss evaluation/proposal status until the source selection process is complete.

6 Acronyms/Abbreviations

ATI	Advanced Technology International
CAS	Cost accounting standards
CM	Consortium Manager
CMA	Consortium Member Agreement
CRMRP	Clinical and Rehabilitative Medicine Research Program
DHA	Defense Health Agency
DHP	Defense Health Program
DoD	Department of Defense
DUNS	Data Universal Numbering System
F&A	Facilities and Administrative Costs
FAQ	Frequently Asked Questions
FDA	Food and Drug Administration
FY	Fiscal Year
G&A	General and Administrative Expenses
IP	Intellectual Property (e.g., patents, copyrights, licensing, etc.)
JPC	Joint Program Committee
M	Million
MTEC	Medical Technology Enterprise Consortium
NDA	Nondisclosure Agreement
OCI	Organizational Conflict of Interest
ODC	Other Direct Costs
pOTA	Prototype Other Transaction Agreement
POC	Point-of-Contact
PPG	Proposal Preparation Guide
Q&A	Questions and Answers
RDT&E	Research, Development, Test, and Evaluation
ROM	Rough Order of Magnitude
RPP	Request for Project Proposals
RTD	Return to Duty
SOW	Statement of Work
TRL	Technology Readiness Level
USAMRMC	U.S. Army Medical Research and Materiel Command
USG	U.S. Government

Attachment 1 - MTEC White Paper Template

General Requirements: Each White Paper is limited to four pages plus a cover page (5 pages total). The White Paper must be in 11 point (or larger) type font, single-spaced, single-sided, on 8.5 inches x 11 inches paper. Smaller font 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 1 inch. The MTEC staff will share white papers with various potential public and private sector sponsors. ***Please do not include confidential or proprietary information.***

Cover Page (1 page)
Title of White Paper

Principal Investigator and Institution

Statement that "This White Paper is submitted pursuant to the RPP MTEC-18-02-OpticNerve"

Indicate which of the following technical focus areas the white paper addresses:

1. Enhance optic nerve regeneration.
2. Re-establish neuronal connections between retinal ganglion cells and the lateral geniculate nucleus with high efficiency.

Dates of submission and signature of official authorized to obligate the institution contractually

Nontraditional Defense Contractor or Nonprofit Research Institution % - (See Attachment 3)

Willingness to allow MTEC Officers access to your White Paper 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. For example, Glaucoma Research Foundation and BrightFocus Foundation support vision research and are interested in co-funding vision projects proposed by MTEC members and selected for funding by the USG through this RPP. Under Nondisclosure Agreements, both Glaucoma Research Foundation and BrightFocus Foundation will have access to white papers and proposals submitted in response to this RPP. Additional private entities may be interested in reviewing certain White Papers within their program areas, allowing opportunities to attract supplemental funding sources. Please indicate your willingness to allow MTEC access to your White Paper for the purposes of engaging in outreach activities with these private sector entities. MTEC staff has signed Nondisclosure Agreements (NDAs) and Organizational Conflict of Interest statements.]

White Paper (4 pages)

Title: [Insert descriptive title of project]

Principal Investigator: [Insert name, institution, email address, phone number]

Background: [Briefly state the clinical problem that the White Paper is addressing.]

Approach: [Briefly describe your approach to solving the problem. Include relevant background data about your approach. Include the current status of your approach.]

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

Technical Strategy: [Outline the proposed methodology in sufficient detail to show a clear course of action.]

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

Military Relavance: [Provide a description of how the proposed technology meets the needs of traumatically injured Service Members]

Dual-Use: [Provide a description of how the proposed technology meets the needs of a civilian population, such as for the treatment of glaucoma or age-related macular degeneration]

Technical Maturity and Commercialization Strategy: [Provide a brief description and justification of the maturity of the proposed technology, anticipated regulatory pathway and commercialization plans. Include information about Intellectual Property/Data Rights Assertions.]

Participants: [Briefly state the qualifications of the Principal Investigator, key personnel, and organizations that will perform the SOW.]

Non-traditional defense contract, 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.]

Period of Performance: [Indicate the total proposed period of performance.]

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.]

Rough Order of Magnitude (ROM) Pricing:
[Required: Indicate the ROM (including indirect costs), and the proposed ROM. This information will be used to provide the Sponsor with a reasonable representation of the amount of funding required to advance the project.] 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 table format below as an example 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*
Subcontractors	*$ 50,000.00*
Consultants	*$ 10,000.00*
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 un-allowable)**	*$ 290,000.00*
Total Project Cost	*$ 579,200.00*

EXAMPLE

Attachment 2 – Nontraditional Defense Contractor or Nonprofit Research Instutions

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.

Nontraditional Defense Contractor or Nonprofit Research Institution Requirements

If the Offeror asserts either (1) it is a nontraditional defense contractor or (2) proposes a nontraditional defense contractor as a team member/subcontractor, or (3) it is a nonprofit research institution, the Offeror shall submit Warranties and Representations (Attachment 4) specifying the critical technologies being offered and/or the significant extent of participation of the nontraditional defense contractor. The nontraditional defense contractor or nonprofit research institution 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* include:

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

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.

Attachment 3 – Cost Share

Cost Sharing includes any costs a reasonable person would incur to carry out (necessary to) proposed projects' statements of work (SOW) not directly paid for by the Government. There are two types of cost sharing: Cash Contribution and In-Kind Contribution. If a proposal includes cost share then it cannot include fee. Cost Share may be proposed only on cost type agreements.

Cash Contribution

Cash Contribution means the Consortium and/or the Research Project Awardee (or Awardees' lower tier subawards) financial resources expended to perform a Research Project. The cash contribution may be derived from the Consortium's or Research Project Awardee (or Awardees' subawards) funds or outside sources or from nonfederal contract or grant revenues or from profit or fee on a federal procurement contract.

An Offeror's own source of funds may include corporate retained earnings, current or prospective Independent Research and Development (IR&D) funds or any other indirect cost pool allocation. New or concurrent IR&D funds may be utilized as a cash contribution provided those funds identified by the Offeror will be spent on performance of the Statement of Work (SOW) of a Research Project or specific tasks identified within the SOW of a Research Project. Prior IR&D funds will not be considered as part of the Offeror's cash.

Cash contributions include the funds the Offeror will spend for labor (including benefits and direct overhead), materials, new equipment (prorated if appropriate), awardees' subaward efforts expended on the SOW of a Research Project, and restocking the parts and material consumed.

In-Kind Contribution

In Kind Contribution means the Offeror's non-financial resources expended by the Consortium Members to perform a Research Project such as wear-and-tear on in-place capital assets like machinery or the prorated value of space used for performance of the Research Project, and the reasonable fair market value (appropriately prorated) of equipment, materials, IP, and other property used in the performance of the SOW of the Research Project.

Prior IR&D funds will not be considered as part of the Consortium Member's cash or
In-Kind contributions, except when using the same procedures as those that authorize Pre-Award Costs, nor will fees be considered on a Consortium Member's cost sharing portion.

Attachment 4 – Stage 2 Evaluation Criteria

For Information Only - Stage 2 Requirement (subject to change)

Stage 2

Compliance Screening

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 by the CM. 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 Section 1.13 above).

Evaluation Process

Stage 2 proposals will be evaluated using a two-tier review process, consisting of scientific peer review and programmatic review, to ensure both scientific excellence and programmatic relevance. First, the scientific peer review will be conducted separately, but concurrently, by each Sponsor (i.e., USAMRMC, Glaucoma Research Foundation, and BrightFocus Foundation) under Nondisclosure Agreements. Second, a programmatic review committee, comprised of the leadership of each Sponsor, will meet to review the outcome of the three scientific peer review panels, recommend a proposal(s) for funding, and discuss strategies for co-funding. Finally, senior leadership at USAMRMC and the Board of Directors of both Foundations will review and finalize the recommendations for funding.

Evaluation Criteria

Selection Overview

To the maximum extent practicable, the following evaluation criteria are anticipated for Full Proposals:

Non-cost/Price Evaluation Criteria:

Technical Merit
Management Approach
Technical Impact
Programmatic Relevance

Cost/Price Evaluation Criteria

The Non-Cost/Price Evaluation Criteria are listed in descending order of importance. When combined the Non-Cost/Price Evaluation Criteria are significantly more important than the Cost/Price Evaluation Criteria.

Non-Cost/Price Evaluation Criteria:

The following criteria will be used to evaluate the non-cost/price aspects of the proposal.

(1) Technical Merit: The technical approach will be evaluated for the degree to which the Offeror demonstrates:

- A written technical approach which effectively demonstrates the Offeror's understanding of the overall requirement, likelihood of successfully achieving the identified Technology Focus Area, and inclusion of complete and clear processes to execute the effort in the required time frame.
- A proposed road map and SOW that is feasible, and includes the rationale, objectives and specific aims to support the research idea.
- An innovative and novel approach to develop new technology that is currently unavailable and offers the possibility of technological breakthroughs.
- A plan to advance the technical maturity level and demonstrate projected performance improvements.
- An approach that is relevant to the specific Technology Focus Area, in support of the overarching goal of developing biomedical products and procedures to protect, project and sustain the force.

(2) Management Approach: The management approach will be evaluated for the degree to which the Offeror's Management Approach demonstrates:

- A written approach to staffing, facilities and resources that will lead to the successful accomplishment of the Technology Focus Area.
- A team of qualified, experienced and knowledgeable staff, with the unique technical and management expertise to carry out the proposed Technology Focus Area, in an efficient and effective manner.
- Clearly identified personnel, facilities and resources that are available to execute the proposed project objectives on schedule.

(3) Technical Impact: The proposal will be evaluated for the degree to which it:

- Advances the state-of-the-art of technology; through research, development and testing, which is needed to develop and transition new materials and improve medical practice for the warfighter.

- Demonstrates potential impact in the research field; the significance of this impact, and the anticipated time period for achievement.
- Demonstrates potential commercial use, and/or movement into the next phase of desired research, development or testing.
- As applicable, demonstrates an achievable approach to regulatory approval (i.e., FDA Approval).

(4) Programmatic Relevance: The proposal will be evaluated for the degree to which it:

- Adheres to the intent of the award mechanism
- Supports overall program portfolio composition
- Supports Military relevance and dual-use purposes
- Relative impact and innovation

(5) Cost Share: The proposal will be evaluated for any Cost Share proposed that is above the minimum statutory requirement of either zero percent cost share (for proposals which include significant participation of a nontraditional defense contractor or nonprofit research institution) and 1/3 cost share (for proposals containing no nontraditional defense contractor or nonprofit research institution participation).

- Cost Share proposed exceeding minimum requirements demonstrates strong non-federal interest in dual use medical technologies.
- Supports a primary Government objective under MTEC to leverage federal funds on proposals that attract non-federal funding sponsors.
- Increases downstream technology commercialization likelihood by securing commitment of additional stakeholders.

Cost/Price Evaluation Criteria

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

(2) Cost/Price Evaluation Process. The MTEC CM will evaluate the estimated cost proposed by the Offeror for performing all requirements outlined in this RPP and the appropriate 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. The Technical Evaluators of the Government, BrightFocus Foundation, and Glaucoma Research Foundation will assess cost realism as part of the source selection process.

- If a proposal(s) is selected for award by the Government, 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.

- If a proposal(s) is selected for award to be co-funded by BrightFocus Foundation and/or Glaucoma Research Foundation, each Foundation will negotiate contracts **directly** with the Offerors selected for award. This will occur concurrently with the Government's process.

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 appropriate 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.

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 Non-Cost/Price 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.

Attachment 5 – Warranties and Representations

For Information Only - Stage 2 Requirement

Authority to use Other Transaction Agreement

Section 815 of the National Defense Authorization Act (NDAA) for Fiscal Year 2018, authorizes Department of Defense organizations to carry out prototype projects that are directly relevant to enhancing the mission effectiveness of military personnel and the supporting platforms, systems, components, or materials proposed to be acquired or developed by the Department of Defense, or to improvement of platforms, systems, components, or materials in use by the armed forces. The law also requires:

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

(B) 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.

(C) 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.

A. Prime Contractor: The prime contractor must complete the following table.

1. Legal Name:		**2. DUNS #:**	
3. Point of Contact: Name, Title, Phone #, Email			
4. Prime Contractor is a nontraditional (Y/N)?			
5. Prime Contractor is a nonprofit research institution (Y/N)?			
6. Prime Contractor will provide at least one third of the total cost of the prototype project out of funds provided by sources other than the Federal Government (Y/N)?			
7. Prime Contractor is a small business (Y/N)?			

If the prime contractor has answered "Y" to question 4, 5, or 6, skip Section B and proceed to Section C.

B. Subcontractor(s)/Vendor(s): If the prime contractor is a **traditional** defense contractor and proposes the use of one or more nontraditional defense contractors or nonprofit research institutions, the following information is required **for each** participating nontraditional defense contractor or nonprofit research institution.

8. Legal Name:		**9. DUNS #:**	

10. Dollar Value to be Awarded:			
11. Point of Contact: **(Name, Title, Phone #, Email)**		**12. Task/Phase:**	
13. Subcontractor/Vendor is a nontraditional (Y/N)?			
14. Subcontractor/Vendor is a nonprofit research institution (Y/N)?			
15. Subcontractor/Vendor is a small business (Y/N)?			
16. Significant Contribution:			

☐	**A - The significant contribution involves developing, demonstrating or providing a key technology.** *Please describe what the key technology is; why it is key to the medical technology community, and what makes it key.*
☐	**B - The significant contribution involves developing, demonstrating or providing a new technology that is not readily available.** *Please describe what the new part or material is and why it is not readily available.*
☐	**C - The significant contribution involves use of skilled personnel (such as modeling & simulation experience, medical technology design experience, etc.), facilities and/or equipment that are within the capabilities of the designated nontraditional and required to successfully complete the program.** *Please describe the personnel, facilities and/or equipment involved in the proposed program and why they are required to successfully complete the program.*
☐	**D - The use of this designated subcontractor/vendor will cause a material reduction in the cost or schedule.** *Please describe the specific cost or schedule impact to be realized*
☐	**E - The use of this designated subcontractor/vendor will increase medical technology performance.** *Please describe what the performance increase will be attained by the use of this designated nontraditional defense contractor*
1	**In addition to the above please provide the following information:**
Q1	**What additional capability beyond those described in A through E above does this subcontractor/vendor have that is necessary for this specific effort?**

A1	
Q2	**In which task/phase(s) of the effort will the subcontractor/vendor be used?**
A2	
Q3	**What is the total estimated cost associated with the subcontractor/vendor included in the proposal?** *Note: While cost is an indicator for the level of nontraditional defense contractor participation, there is no particular cost threshold required.*
A3	

C. Signature

_____ _____

Signature of authorized representative of proposing Prime Contractor Date

Warranties and Representations Instructions

Section A must be completed for the Prime Contractor.

1. Insert prime contractor's legal name.
2. Insert prime contractor's DUNS #.
3. Insert the Point of Contact (Name, Title, Phone #, Email) for the prime contractor.
4. Indicate Yes (Y) or No (N) if the prime contractor is a nontraditional defense contractor (Note: A nontraditional defense contractor means an entity that is not currently performing and has not performed, for at least the one-year period preceding the issue date of the solicitation, any contract or subcontract for the Department of Defense that is subject to full coverage under the cost accounting standards prescribed pursuant to Section 1502 of Title 41 and the regulations implementing such section.).
5. Indicate Yes (Y) or No (N) if the prime contractor is a nonprofit research institution.
6. Indicate Yes (Y) or No (N) if the prime contractor will provide at least one third of the total cost of the prototype project out of funds provided by sources other than the Federal Government (i.e. will the project contain at least 1/3 cost share).
7. Indicate Yes (Y) or No (N) if the prime contractor is a small business (including small businesses participating in a program described under section 9 of the Small Business Act (15 U.S.C. 638)).

Section B must be completed if the Prime Contractor is **traditional** and has proposed nontraditional defense contractors, nonprofit research institutions, or small businesses. Copy, paste, and complete the table found in Section B **for each** participating nontraditional defense contractor, nonprofit research institutions, or small business.

8. Insert subcontractor/vendor's legal name.
9. Insert subcontractor/vendor's DUNS #.
10. Insert the dollar value (cost and fee) to be awarded to the subcontractor/vendor.
11. Insert the Point of Contact (Name, Title, Phone #, Email) for the subcontractor/vendor.
12. Indicate in which specific task/phase(s) of the effort will the subcontractor/vendor be used.
13. Indicate Yes (Y) or No (N) if the subcontractor/vendor is a nontraditional defense contractor (Note: A nontraditional defense contractor means an entity that is not currently performing and has not performed, for at least the one-year period preceding the issue date of the solicitation, any contract or subcontract for the Department of Defense that is subject to full coverage under the cost accounting standards prescribed pursuant to Section 1502 of Title 41 and the regulations implementing such section.).
14. Indicate Yes (Y) or No (N) if the subcontractor/vendor is a nonprofit research institution.
15. Indicate Yes (Y) or No (N) if the subcontractor/vendor is a small business (including small businesses participating in a program described under section 9 of the Small Business Act (15 U.S.C. 638)).
16. Explain the subcontractor/vendor's Significant Contribution to the project by answering the questions below.

A - The significant contribution involves developing, demonstrating or providing a key technology. ***Please describe what the key technology is; why it is key to the medical technology community, and what makes it key***.

B - The significant contribution involves developing, demonstrating or providing a new technology that is not readily available. ***Please describe what the new part or material is and why it is not readily available.***

C - The significant contribution involves use of skilled personnel (such as modeling & simulation experience, medical technology design experience, etc.), facilities and/or equipment that are within the capabilities of the designated nontraditional and required to successfully complete the program. ***Please describe the personnel, facilities and/or equipment involved in the proposed program and why they are required to successfully complete the program.***

D - The use of this designated subcontractor/vendor will cause a material reduction in the cost or schedule. ***Please describe the specific cost or schedule impact to be realized.***

E - The use of this designated subcontractor/vendor will increase medical technology performance. ***Please describe what the performance increase will be attained by the use of this designated nontraditional defense contractor.***

Q1 - What additional capability beyond those described in A through E above does this subcontractor/vendor have that is necessary for this specific effort?

Q2 - In which task/phase(s) of the effort will the subcontractor/vendor be used?

Q3 - What is the total estimated cost associated with the subcontractor/vendor included in the proposal? Note: While cost is an indicator for the level of nontraditional defense contractor participation, there is no particular cost threshold required.

Section C must be signed by an authorized representative of the prime contractor.

General Guidance

- Nontraditional defense contractors can be at the prime level, team members, subcontractors, lower tier vendors, or "intra-company" business units, provided that the business unit makes a significant contribution to the prototype project.
- All nontraditional defense contractors must have a DUNS number.

A foreign business can be considered a nontraditional if it has a DUNS number and can comply with the terms and conditions of the MTEC Base Agreement.

Attachment 6 - MTEC Requirements

For Information Only - Stage 2 Requirement

As a tax-exempt 501(c)(3) entity, MTEC can accept contributions directly from the private sector, including industry partners who wish to co-fund a particular project, philanthropic entities who wish to co-fund a particular project, and/or philanthropic entities who wish to support the overall MTEC mission. Additional MTEC revenue streams for supporting entity operations are membership dues, research assessment fees, and royalty payments.

Per Section 3.4 of the Consortium Member Agreement (CMA), each recipient of a Research Project Award under the MTEC OTA shall pay MTEC an amount equal to 1% of the total funded value of each research project award. Such deposits shall be due no later than 90 days after the research project award is executed. Awardees are not allowed to use MTEC funding to pay for their assessment fees. MTEC has established two methods of payment to be made to MTEC surrounding the licensing/commercialization of Intellectual Property developed with funding received from MTEC Research Project Awards:

Royalty Payment Agreements

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

Additional Research Project Award Assessment

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

Attachment 7 – IP Rights

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 Base Agreements are issued by the MTEC CM to MTEC members receiving Research Project Awards. Base Agreements include the applicable flow down terms and conditions from the Government's Other Transaction Agreement with MTEC, including the IP terms and conditions.

Data Rights

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

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

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