Request for Project Proposals

Solicitation Number: MTEC-23-04-AFIRM

"The Armed Forces Institute for Regenerative Medicine (AFIRM)"

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 27, 2023

Full Proposal Due Date: March 16, 2023
Noon Eastern Time

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 (R&D) activities, in cooperation with the Department of Defense (DoD) U.S. Army Medical Research and Development Command (USAMRDC) 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) engage in biomedical research and prototyping;

(b) exploration of private sector technology opportunities;

(c) technology transfer; and

(d) deployment of intellectual property (IP) and follow-on production.

MTEC is a broad and diverse biomedical consortium that includes representatives from large businesses, small businesses, contract research organizations, "nontraditional" defense contractors, academic research institutions and not-for-profit organizations; for more information on the MTEC mission, see the MTEC website at https://mtec-sc.org/.

MTEC operates under an Other Transaction Agreement (OTA) for prototype projects with USAMRDC. In accordance with 10 USC 4022, the MTEC OTA enables the Government 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 DoD, or to improvement of platforms, systems, components, or materials in use by the armed forces. As defined in the DoD OTA Guide dated November 2018, a prototype project addresses a proof of concept, model, reverse engineering to address obsolescence, pilot, novel application of commercial technologies for defense purposes, agile development activity, creation, design, development, demonstration of technical or operational utility, or combinations of the foregoing. A process, including a business process, may be the subject of a prototype project. Although assistance terms are generally not appropriate in OTAs, ancillary work efforts that are necessary for completion of the prototype project, such as test site training or limited logistics support, may be included in prototype projects. A prototype may be physical, virtual, or conceptual in nature. A prototype project may be fully funded by the DoD, jointly funded by multiple federal agencies, cost-shared, funded in whole or part by third parties, or involve a mutual commitment of resources other than an exchange of funds. Proposed prototype projects should not be exploratory in nature and do require a foundation of preliminary data.

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 U.S.

Combat Casualty Care Research Program (CCCRP) (i.e., Joint Program Committee-6). Proposals selected for award as a result of this RPP will be awarded under the authority of 10 U.S.C. § 4022. Strategic oversight for the award supported by this RPP will be provided by CCCRP.

This RPP aims to develop a multi-institutional, interdisciplinary network of universities, companies, military laboratories, and investigators designed to promote a seamless integration of development, from research through translational and clinical research, as the best means of bringing regenerative medicine therapies to practice. The goal of this program is to accelerate the development of regenerative medicine prototypes to restore function to and heal injured Warfighters using this collaborative network, or consortium. The intent of the RPP is to make a single award to a Coordinating Site that can leverage the combined expertise of the DoD, industry, and academia to advance regenerative medicine prototypes to the clinic.

2 Administrative Overview

2.1. Request for Project Proposals (RPP)

MTEC is utilizing a single-staged approach for this RPP. Each proposal submitted must contain both a Technical and Cost Proposal Volume as described in Section 4 of this RPP and must be in accordance with the mandatory format provided in the MTEC Proposal Preparation Guide (PPG), which is available on the MTEC Members-Only website (https://private.mtec-sc.org/). Proposals that fail to follow the mandatory format provided in the PPG may be eliminated from the competition during the CM's preliminary screening stage (see Section 5 for more details on the Selection process). ***White papers are NOT required for this RPP.*** The Government will evaluate Proposals submitted and will select the proposal that best meets their current priorities using criteria in Section 5 of this RPP. The Government reserves the right to award Proposals received from this RPP on a follow-on prototype OTA or other stand-alone OTAs as necessary to meet mission requirements.

Offerors who submit Proposals in response to this RPP should submit by the date on the cover page of this RPP. Proposals may not be considered under this RPP unless received on or before the due date specified on the cover page.

2.2. Funding Availability and Period of Performance

The U.S. Government (USG) currently has up to **$19.1 million (M)** in Fiscal Year 2022 (FY22) for this program. Additional funding may be later available to the performer to continue prototype development. Award and funding from the Government is contingent upon the availability of federal funds for this program.

Cost sharing, including cash and in kind (e.g., personnel or product) contributions are strongly encouraged, have no limit, and are in addition to the Government funding to be provided under the resultant award(s).

It is expected that MTEC will make **a single award** to a qualified Offeror in FY23 to accomplish the scope of work. Note, however, that the Government reserves the right to make final evaluation and award decisions based upon, among other factors, programmatic relevancy and overall best value solutions determined to be in the Government's best interest. Therefore, if a single Proposal is unable to sufficiently address the entire scope of this RPP's technical and regulatory requirements (outlined in Section 3), several Offerors may be asked to work together in a collaborative manner. However, if an optimal team is not identified, then MTEC may make multiple, individual awards to Offeror(s) to accomplish subset(s) of the key tasks.

The Period of Performance (PoP) is **not to exceed 60 months/5 years**.

Dependent on the results and deliverables under any resultant award(s), the USG may apply additional dollars and/or allow for additional time for non-competitive follow-on efforts with appropriate modification of the award. See Section 3.5 for additional details.

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.

2.3. Acquisition Approach

Full proposals will be required in response to this RPP thus reflecting a single stage acquisition approach. MTEC membership is required for the submission of a full proposal. The due date for Proposals is found on the cover page of this RPP. Proposals may not be considered under this RPP unless the Proposal was received on or before the due date specified on the cover page. The Government will evaluate Proposals submitted and will select those that best meet their current technology priorities using the criteria in Section 5 of this RPP.

Pending successful completion of the total effort, the Government may issue a non-competitive follow-on production contract or transaction pursuant to 10 U.S.C. § 4022 section f.

The Government-selected prototype project(s) awarded as a result of this solicitation will be funded under the OTA for prototype projects Number W81XWH-15-9-0001 with MTEC administered by the CM, ATI. The CM will negotiate and execute a Base Agreement with MTEC members (if not yet executed). The same provisions will govern this Base Agreement as the OTA for prototype projects between the Government and MTEC. Subsequently, any proposal that is selected for award will be funded through a Research Project Award) issued under the member's Base Agreement. The MTEC Base Agreement can be found on the MTEC website (www.mtec-sc.org) and Members-Only website (https://private.mtec-sc.org/).

***At the time of the submission, if Offerors have not yet executed a Base Agreement, then Offerors must certify on the cover page of their Proposal that, if selected for award, they will abide by the terms and conditions of the latest version of the MTEC Base Agreement*.** If the Offeror already has executed an MTEC Base Agreement with the MTEC CM, then the Offeror

must state on the cover page of its Proposal that, if selected for award, it anticipates the proposed effort will be funded under its executed MTEC Base Agreement.

2.4. Proposers Conference

MTEC will host a Proposers Conference that will be conducted via webinar within two (2) weeks after the release of the RPP. The intent of the Proposers Conference is to provide an administrative overview of this RPP process to award and present further insight into the Technical Requirements outlined in Section 3. Further instructions will be forthcoming via email. Offerors are advised to check the MTEC website periodically during the proposal preparation period for any clarifications found in Frequently Asked Questions responses.

2.5. 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. **In accordance with the PPG, please mark all Confidential or Proprietary information as such.** An Offeror's submission of a proposal under this RPP indicates concurrence with the aforementioned CM responsibilities.

Also, as part of MTEC's mission to incorporate philanthropic donations, MTEC frequently makes contact with private entities (e.g., foundations, investor groups, organizations, individuals) that award grants or otherwise co-fund research, and/or operates in research areas that are aligned with those of MTEC. These private entities may be interested in reviewing certain Proposals within their program areas, allowing opportunities to attract supplemental funding sources. Therefore, on your Proposal Cover Page, please indicate your willingness to allow MTEC Officers and Directors access to your Proposal for the purposes of engaging in outreach activities with these private entities. MTEC Officers and Directors who are granted proposal access have signed Nondisclosure Agreements (NDAs) and Organizational Conflict of Interest (OCI) statements. Additionally, these MTEC Officers and Staff represent organizations that currently are not MTEC members, and therefore their parent organizations are not eligible to submit Proposals or receive any research project funding through MTEC. Additionally, all Technical Evaluation Panel participants, which may include contractor support personnel serving as nongovernmental advisors, will agree to and sign a Federal Employee Participation Agreement or a Nondisclosure/Nonuse Agreement, as applicable.

2.6. MTEC Member Teaming

While teaming is not required for this effort, Offerors are encouraged to consider teaming during the proposal preparation period (prior to Proposal submission) if they cannot address the full scope of technical requirements of the RPP or otherwise believe a team may be beneficial to the Government. The following resources may help prime contractors provide a more complete team for this requested scope of work.

2.6.1. MTEC M-Corps

The MTEC M-Corps is a network of subject matter experts and service providers to help MTEC members address the business, technical, and regulatory challenges associated with medical product development. M-Corps offers members a wide variety of support services, including but not limited to: Business Expertise [i.e., business development, business and investment planning, cybersecurity, finance, intellectual asset management, legal, logistics/procurement, pitch deck coaching, transaction advisory], and Technical Expertise [i.e., chemistry, manufacturing and controls, clinical trials, concepts and requirements development, design development and verification, manufacturing, process validation, manufacturing transfer quality management, regulatory affairs]. Please visit https://www.mtec-sc.org/m-corps/ for details on current partners of the M-Corps.

2.6.2. MTEC Database Collaboration Tool

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

- "Collaboration Interests" – Select the type of teaming opportunities your organization would be interested in. This information is crucial when organizations need to search the membership for specific capabilities/expertise that other members are willing to offer.

- "Solicitation Collaboration Interests" – Input specific active solicitations that you are interested in teaming on. This information will help organizations interested in a specific funding opportunities identify others that are interested to partner in regard to the same funding opportunity. Contact information for each organization is provided as part of the member profile in the collaboration database tool to foster follow-up conversations between members as needed.

The Collaboration Database Tool can be accessed via the "MTEC Profiles Site" tab on the MTEC members-only website (https://private.mtec-sc.org/).

2.6.3. Chat Forum

A dedicated chat forum has been established to facilitate direct interaction amongst MTEC members in relation to this active funding opportunity. The chat forum can be accessed via the "Team Portal" on the MTEC members-only website - https://private.mtec-sc.org/.

2.7. Offeror Eligibility

Offerors must be MTEC members in good standing to be eligible to submit a Proposal. Offerors submitting Proposals as **the prime performer must be MTEC members of good standing at least**

3 days prior to submission of the Proposals. Subcontractors (including all lower tier subawardees) do not need to be MTEC members. To join MTEC, please visit http://mtec-sc.org/how-to-join/.

2.8. Cost Sharing Definition

Cost sharing is defined as the resources expended by the award recipients on the proposed statement of work (SOW). *Cost sharing above the statutory minimum is not required in order to be eligible to receive an award under this RPP.* 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 (see **Section 7.4 of the PPG** for definitions); 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.).

2.9. Cost Sharing Requirements

In order to be compliant, Research Projects selected for funding under this RPP are required to meet at least one of the conditions specified in **Section 3 of the PPG**. Beyond that, cost sharing is encouraged, if possible, as it leads to stronger leveraging of Government-contractor collaboration. For more information regarding cost share, please see **Section 7.4 of the PPG**. Proposals that fail to meet the mandatory statutory conditions with regard to the appropriate use of Other Transaction authority, as detailed in **Section 3 of the PPG**, will not be evaluated and will be determined ineligible for award.

2.10. MTEC Assessment Fee

Per Section 3.4 of the Consortium Member Agreement, each recipient of a Research Project Award under the MTEC OTA shall pay MTEC an amount equal to 2% of the total funded value of each research project awarded. Such deposits shall be due no later than 90-days after the Research Project Award is executed. The MTEC Assessment Fee is not considered a direct charge to any resulting award or any other contract. Therefore, Offerors shall not include this Assessment Fee as part of their proposed direct costs. Members who have not paid the assessment fee within 90 days of the due date are not “Members in good standing”.

2.11. Intellectual Property and Data Rights

Baseline IP and Data Rights for MTEC Research Project Awards are defined in the terms of an awardee’s Base Agreement and, if applicable, specifically-negotiated terms are finalized in any resultant Research Project Award. MTEC reserves the right to assist in the negotiation of IP, royalties, licensing, future development, etc., between the Government and the individual performers prior to final award decision and during the entire award period.

The Offeror shall comply with the terms and conditions contained in their Base Agreement regarding IP and Data Rights, as modified by the specifically-negotiated IP and Data rights terms herein. **It is anticipated that anything created, developed, or delivered under this proposed effort will be delivered to the Government with Government Purpose Rights or unlimited data rights unless otherwise asserted in the proposal and agreed to by the Government.** Rights in

technical data in each Research Project Award shall be determined in accordance with the provisions of MTEC Base Agreement.

See **Attachment 6 of the PPG** for more detail. Note that as part of the submitting a Proposal in response to this RPP, **Offerors shall complete and submit Attachment 6 of the PPG (Intellectual Property and Data Rights) as an appendix to the Proposal** with the Signature of the responsible party for the proposing Prime Offeror.

For more information, the CM has published a resource for Offerors entitled, "Understanding Intellectual Property and Data Rights" on the MTEC members-only website.

2.12. Expected Award Date

Offerors should plan on the PoP beginning September of 2023 (subject to change). The Government reserves the right to change the proposed PoP start date through negotiations via the CM and prior to issuing a Research Project Award.

2.13. Anticipated Selection Notification

As the basis of selections is completed, the Government will forward their selections to the MTEC CM to notify Offerors. All Offerors will be notified by email from the MTEC CM of the results of the evaluation. Those successful proposals will move forward with the award process.

Offerors are hereby notified that once a Proposal has been submitted, neither the Government nor the MTEC CM will discuss evaluation/status until after the Offeror receives the formal notification with the results of this evaluation.

3 Technical Requirements

3.1. Background

The initial award mechanism for AFIRM, which was first established in FY08, resulted in awards to two consortia. A second solicitation for AFIRM in FY13 (AFIRM II) resulted in an award to a single consortium. A third solicitation for AFIRM III in FY19 provided funding to partnering project awardees focused on a more narrow technical scope which included only peripheral nerve regeneration and skeletal muscle regeneration. Additional information regarding previous AFIRM awards and performers can be located on the following website: https://afirm.health.mil/.

3.2. Objective

This funding opportunity is intended to support a goal/product-driven consortium of universities, companies, military laboratories, and investigators to accelerate development of regenerative medicine therapies. The award will be made to an organization able to serve as the Coordinating Site of the AFIRM Consortium to facilitate development and translation of regenerative medicine technologies related to Warfighter needs. The intent is to transition several regenerative medicine products over the PoP to the Warfighter and the commercial marketplace. Due to the Coordinating Site's team with specialized expertise, this approach will de-risk technology

development by providing capability/expertise to companies that have promising technologies but lack the ability and experience to bring their technologies to market. This structure also allows flexibility to replace failing prototypes with more promising ones throughout the PoP.

3.3. Award Governance Structure

The intent of the AFIRM Consortium is for the Coordinating Site to work closely together with the CCCRP in an actively coordinated effort to address the regenerative medicine needs of the DoD. The Awardee under this RPP will be managed by the CCCRP, who will be advised by the Executive Advisory Board (EAB). The EAB will be chaired by the CCCRP Program Manager or the CCCRP Director. Awardees shall be prepared to communicate with the CCCRP and the EAB on a routine basis for meetings in-person or "virtually" through video conferences or teleconferences, to:

- Identify and prioritize technology areas of interest in the regenerative medicine field of relevance to the DoD,
- Discuss recommendations for the allocation of funding,
- Discuss regenerative medicine prototype candidates for awards and modifications to awards as part of the AFIRM Consortium,
- Facilitate collaborations with intramural DoD laboratories where appropriate, and
- Provide continuing synchronization and integration of Awardee efforts within the AFIRM consortium and with external stakeholders.

*NOTE: Decision making if other funding partners participate in cost sharing or co-funding will be made by a mutual agreement developed by the CCCRP and those partners/stakeholders. However, the CCCRP will make the final determination of utilization of the DoD resources provided through the Award.

The EAB will meet yearly at a minimum and *ad hoc* as needed. The Coordinating Site shall propose personnel with strong military knowledge of the regenerative medicine space to participate in the EAB. Final appointment and participation to the DoD EAB will be under the purview of the CCCRP.

3.4. Scope of Work

The intent of this RPP is to award the Coordinating Site which will then commence studies after approval from the CCCRP. It is the Government's intent that this initial award will have the potential for significant follow-on funding (pending availability of further funding and technical progress); the initial PoP proposed should not exceed 5 years. All full proposal submissions shall include a projection of the studies with Letters of Intent (LOI) to be conducted by the Consortium over the PoP of the award. Submissions shall also detail how the Offeror will accomplish/achieve all aspects of the requirements to include a clear approach to execute all tasks based upon the Offeror's unique methodology. Therefore, the Offeror shall also clearly identify the major milestones in the SOW/Milestone Payment Schedule (MPS) associated with accomplishing these requirements.

Coordinating Site capabilities to translate regenerative medicine prototypes:
The effort shall be led by a centralized POC at the prime performer to serve as the Coordinating Site. It is possible that several subcontractors will be required to accomplish the full scope of the project and each effort thereunder. Agreements among AFIRM Consortium members shall be handled by the Coordinating Site to the greatest extent possible. A centralized POC for the AFIRM consortium at the Coordinating Site shall be named and will be ultimately responsible for official communication and deliverables. Offerors are expected to propose an AFIRM consortium structure that is comprised of the necessary qualified personnel, facilities, equipment, supplies, services, and subcontractors and related administrative and information technology support to accomplish the objectives. It is preferred that the Coordinating Site have established experience in the advancement and commercialization of technologies related to regenerative medicine; evidence of this experience should be included in the full proposal submission. Furthermore, the Government recognizes that the composition of the team may change as the project requirements evolve over time. Therefore, the Offeror shall include the overall project management plan as part of the full proposal submission. The Offeror shall also describe its strategy to adjust (i.e., expand) the team, as needed, throughout the PoP (to include potential follow-on tasks) to ensure the proper level of effort, access to the necessary subject matter experts, etc.

The Coordinating Site's role may include (but is not limited to) the following activities:

1. Consortium Management
    - Provide the Consortium Director who will be the primary liaison with the Sponsor's Office Technical Representative and the CCCRP.
    - Ensure adherence to planned timelines and milestones.
    - Manage Consortium-developed procedures for prioritization and implementation of studies.
    - Develop, organize, and submit written progress reports and a final written comprehensive report to the USAMRDC.
    - Provide a plan/process for establishing CCCRP-directed collaborations that may be outside of the initial Consortium
2. Market Breadth
    - Describe the Offeror's current network of regenerative medicine technology providers and exemplify the breadth and diversity of regenerative medicine areas of interest with military relevance addressed by the Offeror's current network and how the Offeror plans to continue market research throughout the PoP.
3. Project portfolio expansion
    - Implement an objective technical review process for the evaluation of project information papers. Information papers will undergo a two tiered evaluation process that includes a highly competent technical evaluation panel, followed by discussion and prioritization by the EAB which will serve as the programmatic review panel. The Offeror is required to propose a technical evaluation panel (TEP) that is objective and represents a diverse set of organizations so that a single organization does not have the majority viewpoint. The TEP must include people with different focus areas of

interest, strengths, and organizational ties. The Offeror must also present a comprehensive conflict of interest (COI) plan and will be expected to manage/mitigate any COIs (including the perception of COIs). Full evaluation of the portfolio of projects will be executed by the CCCRP and the EAB. All regenerative medicine prototype projects will require approval by the CCCRP prior to addition to the AFIRM Consortium award.

4. Support the development activities required to advance prototypes related to regenerative medicine along their maturation pipeline. It will be the responsibility of the Coordinating Site to seek, initiate, and manage commercial partnerships. The consortium is expected to leverage institutional capabilities or partners, or to employ external resources to identify and promote commercial collaboration. The Offeror shall propose how to address specific challenges related to regenerative medicine prototype development and provide Letters of Support in their proposal from organizations of interest, including but not limited to:
    - Non-clinical testing (to include pre-clinical, bench, and animal testing)
    - Biocompatibility studies
    - Prototype refinement/maturation progressing toward a clinical product
    - Stability and shelf-life studies
    - Establishment of Good Manufacturing Practice capabilities for clinical trials and for market release [Contract Manufacturing Organization capabilities]
    - Clinical feasibility and pivotal studies (as needed) to support regulatory approval/clearance
    - Regulatory and reimbursement strategy
    - Clinical Research Organization capabilities
    - Regulatory affairs and compliance capabilities
    - Investigational New Drug/ Investigational Device Exemption Holder /Sponsor responsibilities as per 21CFR312 subpart D
    - Prototype delivery for military-relevant testing, if required
    - Draft product support documentation (e.g., training guides, product inserts, etc.)
    - Development of a business and/or commercialization plan for market release
5. With coordination with CCCRP, oversee and manage the project portfolio to enhance the likelihood of prototype success
    - Conduct strategic planning to ensure successful transition of candidate prototypes to the commercial marketplace and the Warfighter
    - Provide resources and collaborative events for early translational activities, such as team building, strategy, project management and planning, etc.
    - Conduct routine (e.g., Quarterly and/or Milestone) performance reviews
    - Provide routine technical and programmatic review of projects
    - Make recommendations to the EAB for approval regarding project status (e.g., termination, modification, continuation, changes to SOWs, re-partnering, terminations, reallocation of funding to current projects, etc.)
6. Results dissemination
    - Conduct a yearly symposium that brings together key personnel from the Government, projects, and other key stakeholders. [Offerors should plan for this to

be tagged onto the MTEC Annual Membership Meeting or Military Health System Research Symposium.]

- Manage Consortium-developed procedures for the timely publication of major findings and other public dissemination of data.
- Publish a yearly report that summarizes performance

Proposed regenerative medicine prototypes must meet the following criteria:

1. Prototype Maturity: The AFIRM consortium is expected to propose a portfolio of regenerative medicine prototypes that span the pipeline of maturity, ranging from Technology Readiness Levels (TRLs) of TRL 3 to TRL 7.
2. Types of Prototypes: Proposed regenerative medicine prototypes may span the breadth of the FDA classification list, including devices, drugs, biologics, combinations thereof, etc.
3. Military Relevance: The ultimate goal of this program is to accelerate the development of regenerative medicine prototypes to heal and restore injured Warfighters. Events in the Russia-Ukraine War have emphasized the need to change the trajectory of healing by providing better solutions closer to the point of need that can provide the framework for restoring form and function to combat casualties. Proposed prototypes must be relevant to the health care needs of the DoD and fall under one of the following focus areas:
   - Craniomaxillofacial Regeneration
   - Extremity Regeneration (bone, muscle, and/or nerve)
   - Genitourinary/Lower Abdomen Reconstruction
   - Skin Regeneration
   - Ex-vivo/on-demand blood
   - Cellular therapies for trauma and critical care
4. Commercial Partners: It is preferred that proposed prototypes shall include partnerships with commercial entities/industry partner(s) committed to bringing the product to market.
5. PoP: PoP for each proposed prototype shall not exceed the PoP of the award.

3.5. Potential Follow-on Tasks

Under awards resulting from this RPP, there is the potential for award of one or more non-competitive follow-on tasks based on the success of the project (subject to change depending upon Government review of completed work and successful progression of milestones). Potential follow-on work may be awarded based on the advancement in prototype maturity during the PoP. Potential follow-on tasks may include (but are not limited to) the continued development of prototypes and/or inclusion of additional prototypes related to Warfighter regenerative medicine needs. Further development opportunities will be open and coordinated by the AFIRM Consortium's Coordinating Site through MTEC.

3.6. Restrictions on Animal and Human Subjects

Proposals must comply with the above-mentioned 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 IRB, but at a minimum, annually), and approval by the USAMRDC Office of Human and Animal Research Oversight (OHARO) Office of Human Research Oversight (OHRO). Offerors shall include IRB and OHRO review and approval in the SOW/Milestones Table submitted with the Stage 2 full proposal (if invited), as applicable.

Research Involving Humans: All DoD-funded research involving new and ongoing research with human anatomical substances, human subjects, or human cadavers must be reviewed and approved by the USAMRDC OHRO prior to research implementation. This administrative review requirement is in addition to the local IRB or Ethics Committee review. Allow a minimum of 2 to 3 months for OHRO regulatory review and approval processes.

Research Involving Animals: All DoD-funded research involving new and ongoing research with animals must be reviewed and approved by the USAMRDC OHARO Animal Care and Use Review Office (ACURO), in addition to the local Institutional Animal Care and Use Committee (IACUC) of record. Allow at least 3 to 4 months for ACURO regulatory review and approval processes for animal studies.

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

The USAMRDC OHRO will issue written approval to begin research under separate notification. Written approval to proceed from the USAMRDC OHRO 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 30 days in their schedule for the ORP review and authorization process.

3.7. Guidance Related to DoD-Affiliated Personnel for Participation

Compensation to DoD-affiliated personnel for participation:
Please note that compensation to DoD-affiliated personnel for participation in research while on duty is prohibited with some exceptions. For more details, see Department of Defense Instruction (DODI) 3216.02, Protection of Human Subjects and Adherence to Ethical Standards in DoD-Conducted and -Supported Research. You may access a full version of the DODI by accessing this link: https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/321602p.pdf

4 Proposal Preparation

4.1. General Instructions

Proposals should be submitted by the date and time specified on the cover page using Broad agency announcement Information Delivery System (BIDS): https://ati2.acqcenter.com/ATI2/Portal.nsf/Start?ReadForm. See **Attachment 7 of the PPG** for further information regarding BIDS registration and submission. The Offeror shall include MTEC Solicitation Number (**MTEC-23-04-AFIRM**) on the submitted proposal.

The MTEC PPG is specifically designed to assist Offerors in understanding the proposal preparation process. The Proposal format outlined in **Section 6 of the PPG** is mandatory and shall reference this RPP number (**MTEC-23-04-AFIRM**). Offerors are encouraged to contact the POCs identified herein up until the Proposal submission date/time to clarify requirements (both administrative and technical in nature).

All eligible Offerors may submit Full Proposals for evaluation according to the criteria set forth herein. Offerors are advised that only ATI as the MTEC's CM, with the approval of the DoD Agreements Officer, is legally authorized to contractually bind MTEC into any resultant awards.

4.2. Instructions for the Preparation & Submission of the Proposal

Offerors submitting a Proposal in response to this RPP shall prepare all documents in accordance with the following instructions:

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, searchable, and without a password required. Filenames must contain the appropriate filename extension (.docx, .doc, .pptx, .ppt .xlsx, .xls or .pdf). Filenames should not contain special characters. Apple users must ensure the entire filename and path are free of spaces and special characters.

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

Required Submission Documents (9): Submitted via BIDS (5MB or lower per document)

- **Technical Proposal:** one PDF document **(Refer to Section 6.2 of the PPG)**
- **Section I: Cost Proposal Narrative:** one Word or PDF document **(Refer to Section 7.2 of the PPG)**
- **Section II: Cost Proposal Formats:** one Excel or PDF document **(Refer to Section 7.3 of the PPG)**
- **Warranties and Representations:** one Word or PDF document **(Attachment 3 of the PPG)**
- **SOW/MPS:** one Word or PDF document (**Attachment 4 of the PPG**)
- **Current and Pending Support:** one Word of PDF document **(Attachment 5 of the PPG)**
- **IP and Data Rights Assertions:** one Word or PDF document (**Attachment 6 of the PPG**)
- **Data Sharing and Consortium IP Policy:** one PDF document
- **Letters Of Intent (LOI):** one PDF document

What follows provides additional information related to each of the required documents for the full proposal submission. The Technical Proposal and the Cost Proposal must be submitted in two

separate volumes, and shall remain valid for 180 days unless otherwise specified by the Offeror in the proposal. Offerors are encouraged to contact MTEC with any questions so that all aspects are clearly understood by both parties. The Proposal should include the following. Each document will be uploaded to BIDS separately **(see Attachment 7 of the PPG for BIDS instructions)**.

- **Technical Proposal:** The Technical Proposal (also referred to as Volume 1) shall adhere to the format provided in the MTEC PPG is mandatory and shall be limited to thirty (30) pages, **excluding** the *Cover Page, MTEC Member Organization Information Sheet, Table of Contents, List of Figures and Tables, and Bibliography*. 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 1 inch. Offerors are strongly encouraged to use pictures and graphics to succinctly represent proposed ideas, organization, etc. Proposals shall reference this RPP number (**MTEC-23-04-AFIRM**). Refer to section 6.2 of the PPG for instructions regarding the format of the Technical Proposal. **Full Proposals and Appendices exceeding the page limitations and/or the file size specified above may not be accepted.**

APPENDICES (excluded from the page limit, and must be uploaded to BIDS as separate documents)

- **Cost Proposal:** The Cost Proposal (also referred to as Volume 2) should clearly delineate your costs separated by focus area (if applicable), where possible. Each cost proposal should include direct costs and other necessary components as applicable, for example, fringe, General & Administrative Expense, Facilities & Administrative, Other Direct Costs, etc. Offerors shall provide a breakdown of material and ODC costs as applicable. The Cost Proposal shall be submitted in two separate sections - Section I: Cost Proposal Narrative and Section II: Cost Proposal Formats. [Refer to Section 7 of the PPG for instruction regarding the preparation of the Cost Proposal.] Cost proposal formats are available on the Members-Only MTEC website, however these formats are **NOT** mandatory. **Offerors are encouraged to use their own cost formats such that the necessary detail is provided.** Refer to the MTEC PPG for additional details. Refer to Section 5.3 of this RPP for details on how the full Cost Proposals will be evaluated.

- **Warranties and Representations (template provided in Attachment 3 of the PPG):** Warranties and Representations are required. One Word (.docx or .doc) or PDF file that contains all Warranties and Representations is required.

- **SOW/MPS (template provided in Attachment 4 of the PPG)**:
    - Provide a draft SOW as a separate Word document to outline the proposed technical solution and demonstrate how the contractor proposes to meet the Government objectives. Submitted information is subject to change through negotiation if the Government selects the Proposal for award. The format of the

proposed SOW shall be completed in accordance with the template provided below.
    - The Government reserves the right to negotiate and revise any or all parts of SOW/ MPS. Offerors will have the opportunity to concur with revised SOW/MPS as necessary.

- **Current and Pending Support (template provided in Attachment 5):** The Offeror shall provide this information for all key personnel who will contribute significantly to the proposed research project. Specifically, information shall be provided for all current and pending research support (to include Government and non-government), including the award number and title, funding agency and requiring activity's names, period of performance (dates of funding), level of funding (total direct costs only), role, brief description of the project's goals, and list of specific aims. If applicable, identify where the proposed project overlaps with other existing and pending research projects. Clearly state if there is no overlap. If there is no current and/or pending support, enter "None."

- **IP and Data Rights Assertions (template provided in Attachment 6)**
    - The Offeror shall comply with the terms and conditions defined in the Base Agreement regarding Data Rights. It is anticipated that anything delivered under this proposed effort would be delivered to the Government in accordance with Section 2.11 of the RPP unless otherwise asserted in the proposal and agreed to by the Government.
    - If this is not the intent, then you should discuss any restricted data rights associated with any proposed deliverables/milestones. If applicable, complete the table within the referenced attachment for any items to be furnished to the Government with restrictions.

- **Data Sharing and Consortium IP Policy (no template provided)**
    - Describe a policy for how the Coordinating Site expects to work with and handle other technology providers bringing in their own IP.
    - Present a data sharing plan that will be adopted by the AFIRM consortium (Coordinating Site as the prime contractor and technology providers as subcontractors).
    - Describe a policy for how results funded under this award will be publicly presented and/or published (e.g., conferences peer-reviewed publications, press releases).

- **Letters of Intent**
    - Provide a letter of intent for at least 3 prototypes, but no more than 10 prototypes, to be considered for execution by the AFIRM Consortium. The intent of this appendix is for the Integrator to demonstrate a portfolio of prototypes that fit the technical scope of work requested in this RPP, of which several can be selected for award.
    - Each LOI has a 2-page maximum and must include the following information:

- Describe how the proposed prototype meets the needs specified in this RPP.
- Describe the scientific rationale for the project.
- Define the scope of the effort and clearly state the objectives of the project.
- Provide a description of the anticipated outcomes or deliverables from the proposed work.
- Briefly describe the team/organizations that will perform the proposed work.
- Indicate the proposed PoP in months from award.
- Describe cost share included to support the proposed scope of work.
- Provide a yearly estimate based on the technical approach proposed
- Signature by an authorized representative of the organization with legal authority to develop the proposed prototype.

Evaluation: The Government will evaluate and determine which proposal(s) to award based on criteria described in **Section 5, "Selection,"** of this RPP. The Government reserves the right to negotiate with Offerors.

4.3. Full Proposal Preparation Costs

The cost of preparing Full Proposals in response to this RPP is not considered a direct charge to any resulting award or any other contract. Additionally, the MTEC Assessment Fee (see Section 2.10 of this RPP) is not considered a direct charge to any resulting award or any other contract.

4.4. Freedom of Information Act

To request protection from Freedom of Information Act disclosure as allowed by 10 U.S.C. §552. Offerors shall mark business plans and technical information with a legend identifying the documents as being submitted on a confidential basis. For more information, please refer to Section 6.1.1 of the MTEC PPG.

4.5. Telecommunications and Video Surveillance

Per requirements from the Acting Principal Director of Defense Pricing and Contracting dated 13 August 2020, the provision at FAR 52.204-24, "Representation Regarding Certain Telecommunications and Video Surveillance Services or Equipment" is incorporated in this solicitation. If selected for award, the Offeror(s) must complete and provide the representation, as required by the provision, to the CM.

5 Selection

5.1 Preliminary Screening

The CM will conduct a preliminary screening of submitted 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. Additionally, the Government reserves the right to request additional information or eliminate proposals that do not meet these requirements from further consideration. One of the primary reasons for non-compliance or elimination during the initial screening is the lack of significant nontraditional defense contractor participation, nonprofit research institution participation, or cost share (see Section 3 of the PPG). Proposal Compliance with the statutory requirements regarding the appropriate use of Other Transaction Authority (as detailed within Section 3 of the PPG) will be determined based upon the ratings 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 Proposal has at least one Nontraditional Defense Contractor or Nonprofit Research Institute participating to a significant extent • All significant participants in the transaction other than the Federal Government are small businesses or nontraditional defense contractors • Offeror provides at least one third of the total project cost as acceptable cost share
FAIL	Offeror proposing an MTEC research project does **NOT** meet at least ONE of the following: • Offeror is a Nontraditional Defense Contractor or Nonprofit Research Institution • Offeror's Proposal has at least one Nontraditional Defense Contractor or Nonprofit Research Institution participating to a significant extent • All significant participants in the transaction other than the Federal Government are small businesses or nontraditional defense contractors • Offeror provides at least one third of the total project cost as acceptable cost share

5.2 Proposal Evaluation

The CM will distribute all Proposals that pass the preliminary screening (described above and in Table 1) to the Government for full evaluation. Evaluation of proposals will be based on an independent, comprehensive review and assessment of the work proposed against stated source selection criteria and evaluation factors. The Government will evaluate each Proposal against the

evaluation factors detailed below and assign adjectival ratings to the non-cost/price factor(s) consistent with those defined in Table 2 (General Merit Rating Assessments). The Offeror shall clearly state how it intends to meet and, if possible, exceed the RPP requirements. Mere acknowledgement or restatement of a RPP requirement is not acceptable. The overall award decision will be based upon a best value determination by considering factors in addition to cost/price.

The evaluation factors and evaluation criteria are described below and are of equal importance.

Evaluation Factors

1. **Technical Approach**
2. **Project Management and Experience**
3. **Cost Reasonableness**

Evaluation Factor 1 – Technical Approach:
This factor will evaluate the relevancy, thoroughness, completeness, and impact of the proposed approach (e.g., the technical merit) and how well the proposal defines and meets the requirement of the Coordinating Site's role and function. The following will be considered:

- Soundness and clarity of the scientific rationale with supporting preliminary data and demonstrated proof-of-concept.
- How well the proposed methodology and statement of work supports the technical objectives and development of the prototype.
- How well the approach demonstrates the Offeror's understanding of the overall military relevance, such as the health care needs of military Service members, enhanced capabilities of their care providers, and training requirements.
- Proposed projects will be assessed for relevancy, thoroughness, and completeness of the proposed approach (e.g., the technical merit).
- LOIs will be assessed for relevancy to needs described in this solicitation, the objectives and scope, and anticipated outcomes.
- How well the proposed SOW addresses the technical requirements described in Section 3 of this RPP.

Evaluation Factor 2 – Project Management and Experience:
This factor will evaluate the project team's expertise, personnel identified as key (those who will contribute significantly to the proposed research project), and experience shall demonstrate an ability to execute the SOW in an efficient and effective manner (to include addressing USAMRDC's OHARO approval requirements). The schedule will be evaluated to determine whether the proposed work is realistic and reasonable within the proposed period of performance. This factor will also include evaluation of the Offeror's current network in the field to include technology providers and service providers. The following will be considered:

- Appropriateness of the proposed overall organizational structure of the Consortium for rapid development of products.
- Effectiveness of management and communication plans.

- Experience, expertise, track record of Coordinating Site and proposed Consortium members.

Factor 3 – Cost Reasonableness: Assessment of the cost of the project to determine: i) whether the project cost is within the available funding limits, and ii) the ability and/or likelihood of the offeror to successfully execute the proposed project within the financial resources proposed. The proposed cost will be based on the following ratings: Sufficient, Insufficient or Excessive. See the definitions of these ratings in Table 3 below.

With the exception of "Cost Reasonableness," evaluation factors will be rated based upon the adjectival merit ratings detailed in Table 2. See Table 3 for the definitions of the "Cost Reasonableness" factor ratings.

Table 2 explains the adjectival merit ratings that will be used for the Evaluation Factors.

TABLE 2 - GENERAL MERIT RATING ASSESSMENTS	
RATING	**DESCRIPTION**
OUTSTANDING	Proposal meets requirements and indicates an exceptional approach and understanding of the requirements. Strengths far outweigh any weaknesses. Risk of unsuccessful performance is very low.
GOOD	Proposal meets requirements and indicates a thorough approach and understanding of the requirements. Proposal contains strengths which outweigh any weaknesses. Risk of unsuccessful performance is low.
ACCEPTABLE	Proposal meets requirements and indicates an adequate approach and understanding of the requirements. Strengths and weaknesses are offsetting or will have little or no impact on contract performance. Risk of unsuccessful performance is no worse than moderate.
MARGINAL	Proposal does not clearly meet requirements and has not demonstrated an adequate approach and understanding of the requirements. The proposal has one or more weaknesses which are not offset by strengths. Risk of unsuccessful performance is high.
UNACCEPTABLE	Proposal does not meet requirements and contains one or more deficiencies. Proposal is not awardable.

TABLE 3- "COST REASONABLENESS" FACTOR RATINGS DEFINITIONS	
RATING	**DESCRIPTION**

SUFFICIENT	The estimate is within the available funding limits and considered appropriate to successfully complete the proposed project
INSUFFICIENT	The estimate is lower than what is considered appropriate to successfully complete the proposed project.
EXCESSIVE	The estimate is higher than what is considered appropriate to successfully complete the proposed project and may be outside of the available funding limits.

Please also refer to Section 5.4 for definitions of general terms used in technical evaluations.

Upon review and evaluation of the Proposals, the Government sponsor will perform proposal source selection. This will be conducted using the evaluation factors detailed above. The Government will conduct an evaluation of all qualified proposals. The Source Selection Authority may:

1. ***Select the proposal (or some portion of the proposal) for award***
2. ***Place the proposal in the Basket if funding currently is unavailable; or***
3. ***Reject the proposal (will not be placed in the Basket)***

The RPP review and award process may involve the use of contractor subject matter experts (SMEs) serving as nongovernmental advisors. All members of the technical evaluation panel, to include contractor SMEs, will agree to and sign a Federal Employee Participation Agreement or a Nondisclosure/Nonuse Agreement, as appropriate, prior to accessing any proposal submission to protect information contained in the Proposal as outlined in Section 2.5.

5.3 Cost/Price Evaluation by the Consortium Manager

After completion of the technical evaluation performed by the Government sponsor, the MTEC CM will evaluate the cost proposed together with all supporting information for realism, reasonableness, and completeness as outlined below. If a proposal is selected for award, the MTEC CM will provide a formal assessment to the Government at which time the Government will make the final determination that the negotiated project cost is fair and reasonable.

a) **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 technical approach and SOW.

Estimates are “realistic” when they are neither excessive nor insufficient for the effort to be accomplished. Estimates must also be realistic for each task of the proposed project when compared to the total proposed cost. For more information on cost realism, please refer to the MTEC PPG.

The MTEC CM will make a determination by directly comparing proposed costs with comparable current and historical data, evaluator experience, available estimates, etc. Proposed estimates will be compared with the corresponding technical proposals for consistency.

b) **Reasonableness**. The Offeror's cost proposal will be evaluated to determine if it is reasonable. For a price to be reasonable, it must, in its nature and amount, 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. If the MTEC template is not used, the Offeror should submit a format providing for a similar level of detail.

c) **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.

Government Access to Information
After receipt of the cost proposal and after the CM's completion of the cost analysis summarized above, the government may perform a supplemental cost and/or price analysis of the submitted cost proposal. For purposes of this analysis, the Agreement Officer and/or a representative of the Agreement Officer (e.g., Defense Contract Audit Agency, Defense Contract Management Agency, etc.) shall have the right to examine the supporting records and/or request additional information, as needed.

Best Value

The overall award decision will be based upon the Government's Best Value determination and the final award selection(s) will be made to the most advantageous offer(s) by considering and comparing factors in addition to cost or price. The Government reserves the right to negotiate and request changes to any or all parts of the proposal, to include the SOW.

5.4 Definition of General Terms Used in Evaluations

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.

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 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.

6 Points-of-Contact

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

- Questions concerning contractual, cost or pricing related to this RPP should be directed to the MTEC Contracts Administrator, mtec-contracts@ati.org
- Technical and membership questions should be directed to the MTEC Biomedical Research Associate, Dr. Chuck Hutti, Ph.D., chuck.hutti@ati.org
- All other questions should be directed to the MTEC Chief of Consortium Operations, Ms. Kathy Zolman, kathy.zolman@ati.org

7 Acronyms/Abbreviations

AFIRM	Armed Forces Institute for Regenerative Medicine
ATI	Advanced Technology International
BIDS	Broad agency announcement Information Delivery System
CCCRP	Combat Casualty Care Research Program
CM	Consortium Manager
COI	Conflict of Interest
DoD	Department of Defense

DODI	Department of Defense Instruction
EAB	Executive Advisory Board
FY	Fiscal Year
Government	U.S. Government, specifically the DoD
IP	Intellectual Property (e.g., patents, copyrights, licensing, etc.)
IRB	Institutional Review Board
M	Millions
MPS	Milestone Payment Schedule
MTEC	Medical Technology Enterprise Consortium
NDA	Nondisclosure Agreement
OCI	Organizational Conflict of Interest
OHARO	Office of Human and Animal Research Oversight
OHRO	Office of Human Research Oversight
OTA	Other Transaction Agreement
PDF	Portable Document Format
POC	Point-of-Contact
PoP	Period of Performance
PPG	Proposal Preparation Guide
R&D	Research and Development
RPP	Request for Project Proposals
SME	Subject Matter Expert
SOW	Statement of Work
TEP	Technical Evaluation Panel
TRL	Technology Readiness Level
USAMRDC	U.S. Army Medical Research and Development Command
USG	U.S. Government