

Request for Project Proposals



Solicitation Number: MTEC 18-04-I-PREDICT
“Incapacitation Prediction for Readiness in Expeditionary Domains: an Integrated Computational Tool (I-PREDICT)”

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

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White Papers Are NOT Required

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1 Executive Summary

1.1 The Medical Technology Enterprise Consortium

The Medical Technology Enterprise Consortium (MTEC) is an enterprise partnership in collaboration with industry and academia to facilitate research and development activities, in cooperation with the U.S. Army Medical Research and Materiel Command (USAMRMC) and other Government agencies in the biomedical sciences (including but not limited to drugs, biologics, vaccines, medical software and medical devices) to protect, treat and optimize the health and performance of U.S. military personnel. MTEC is a nonprofit corporation with the following principal objectives:

- (a) biomedical research and prototyping;
- (b) exploration of private sector technology opportunities;
- (c) technology transfer; and
- (d) deployment of intellectual property (IP) and follow-on production.

MTEC is openly recruiting members to join a broad and diverse biomedical consortium that includes representatives from large businesses, small businesses, contract research organizations, “nontraditional” government contractors, academic research institutions and not-for-profit organizations; for more information on the MTEC mission, see the Proposal Preparation Guide (PPG) and MTEC website.

1.2 Purpose

This solicitation, issued by the MTEC Consortium Manager (CM), represents a Request for Project Proposals (RPP) for MTEC’s support of the Office of Naval Research (ONR) Incapacitation Prediction for Readiness in Expeditionary Domains: an Integrated Computational Tool (I-PREDICT) Force Health Protection Future Naval Capability (FNC) project. Strategic oversight for the award(s) supported by this RPP will be provided by the ONR Code 34 Warfighter Performance Department and its support team.

The purpose of the I-PREDICT FNC is to provide a Technology Readiness Level (TRL) 6 *in silico*, “*skin-in*” integrated finite element computational model of the Warfighter’s body that will predict immediate injury and near term functional incapacitation (reduction in the ability to move, shoot, and/or communicate) resulting from exposure to specific military hazards. **This particular solicitation is focused on acquiring a finite element computational model of the thorax to predict injury and functional incapacitation from behind armor blunt trauma, as an initial step toward whole-body modeling of responses to a variety of military hazards.**

Experimentally derived injury risk criteria and functional incapacitation risk criteria will be used to evaluate the risk of thorax injury and its potential functional consequences. Wherever

possible, injury risk criteria and incapacitation risk criteria will be identified from existing scientific literature on injury biomechanics relevant to the military population exposed to high-rate loading threats and will employ associated validation datasets. Additional experimental work will be performed as part of the project to obtain more biofidelic high strain rate constitutive properties for organs and tissues of the thorax.

2 Overview of the Intended System

The description below provides an overview of the intended long-term capabilities of the I-PREDICT FNC. It is expected that Offerors consider this vision when responding to this RPP. Although this specific solicitation (18-04-I-PREDICT) is seeking proposals on experimental and modeling capabilities for injuries and functional incapacitation as a result of behind armor blunt trauma, it is important that your proposed solution allows for future expansion of the model such that all the capabilities outlined below can be achieved.

Injury and incapacitation estimates for combat scenarios are currently educated guesses at best. Estimates may be based on simplified injury risk thresholds on hazard parameters such as pressure, stress, strain, or force applied to an organ or tissue. Increasingly, such knowledge is incorporated into computational simulations that can be run repeatedly to explore variations in hazards and physiologic responses in order to assign statistical confidence to predictions of injury risk. Current modeling and simulation methods for predicting injury can be inaccurate, regional rather than whole-body, not validated appropriately, and may not be based upon physiologically or operationally relevant loading conditions. Injury prevention standards are needed to protect Warfighters from injuries based on a scientific understanding of hazardous conditions typical of military service, and of the vulnerability of tissues, organs, and bodily functions to those hazards. Such standards will inform the design trade spaces of personal protective equipment (PPE), safer vehicles, and safe-to-operate weapons systems; as well as tactics, techniques, and procedures (TTPs) to protect against injury. Injury prediction models will also allow improved estimation of casualty types, rates and severity, which in turn will predict individual and unit readiness during operations and medical treatment requirements. The development of a highly biofidelic finite element model of the whole human body is needed to inform such applications.

Many of the experimental studies used to parameterize human body computational models have employed cadaveric tissue, which may not adequately represent the biomechanical responses of live human tissue due to donor age, cause of death, post-mortem degradation, altered tissue properties due to hypothermic test conditions, and isolation of test samples from surrounding structures found *in vivo*. More biofidelic constitutive properties that better represent living human tissue are needed to support model parameterization in support of improved predictions of injury and functional incapacitation. Consequently, ONR research efforts are under way developing new methodologies for more accurate measurements of constitutive properties of human and surrogate (animal model) tissues both *ex vivo* and *in vivo* across a wide range of strain rates.

Accurate use and calibration of component constitutive models remain obstacles for predictive modeling due to lack of reliable sample material data. Recent and continued advances in characterization standards and experimental methods are needed to account for material anisotropy, rate dependence, multiphase composition, specimen variability, multiphysics, and multiscale behavior.

The overarching goal of the of the I-PREDICT FNC is to provide a TRL 6 *in silico* “skin-in” integrated finite element computational model of the Warfighter’s body to be used for injury prevention and treatment, medical response planning, and equipment design including tradeoff analysis among design parameters, validation, and testing. The I-PREDICT FNC will provide an integrated biomechanical response model of the Warfighter using biofidelic constitutive tissue properties, and associated pre- and post-processing tools that will predict injury and near term functional incapacitation (reduction in the ability to move, shoot, and/or communicate) in response to specific military hazards, in priority order of: 1) blunt impact/accelerative loading and 2) blast pressure effects. The model will be based on experimentally derived material properties of human tissues at strain rates equivalent to those experienced during military hazards, and will be validated with data on regional and whole-body mechanics. I-PREDICT will include variable anthropometry (e.g., differences in size, weight, somatotype, and age), variable posture, variable biofidelity, and gender differences in modeling. The results will be incorporated into injury and readiness estimates into medical response planning and preliminary design and testing of equipment, resulting in cost savings and more thoroughly vetted products that have made principled considerations for engineering tradeoffs (e.g., weight of body armor vs. mobility).

2.1 Behind Armor Blunt Trauma Use Case for the Thorax

This initial RPP solicits experimental and modeling proposals to advance the state of the art in prediction of injury and incapacitation due to behind armor blunt trauma (BABT) of the thorax, as an initial focused use case representing an operational military need. Body armor, for example the Improved Outer Tactical Vest (IOTV) and Small Arms Protective Insert (SAPI) ballistic plates, are worn by Warfighter personnel to protect against injury largely from penetrating ballistic fragments, including rifle or handgun rounds, engineered grenade fragments, shrapnel from vehicles or other equipment subject to explosive hazards, or incidental particles such as rocks and dust accelerated by explosions. BABT refers to the spatially distributed energy from larger fragments with high momentum reaching the body that result from the protective effects of the armor. Penetrating ballistic injuries resulting from armor overmatch will not be addressed.

Existing design standards for protective equipment currently depend on the physical measurement of the depth of backface deformation into a physical surrogate for the human torso. The physical surrogate, consisting of a block of clay to which protective equipment (armor) has been affixed, is subjected to live fire from specific firearms striking the armor orthogonally, i.e., at right angles to the face of the armor. The depth of deformation in the clay is used as a

proxy for the likelihood of serious injury, and used to explore tradeoffs in the design space of protection, weight, encumbrance, and comfort. Typically, a deformation of 44 mm is considered serious. The need for a more biofidelic proxy for human injury has long been recognized. This solicitation seeks to advance practice in the use of a virtual or computational surrogate for injury risk assessment with high biofidelity, with validating physical experiments beyond what exists in the literature today.

It is not the intent of I-PREDICT to model equipment. Computational models of the thorax should assume proper armor fit (i.e., the ability to breathe and move) and enable high-rate loading inputs directly to the skin that account for the dissipating effects of body armor. As such, these inputs should be able to be applied as the resultant forces and deformations on the thorax under the armor following an impact.

An existing government-owned parameterized finite element model of the human torso will be made available to performers as a reference implementation, and as a baseline model subject to improvement. See section 5.3 for additional details. A performer will be expected to adapt the reference implementation through parameterization using new or alternatively sourced constitutive response data, validating BAPT experiments resulting in kinematic and/or stress/strain data, and/or injury biomechanics data. Validating experiments of interest should prioritize high-powered antipersonnel rounds to the anterior and/or posterior surfaces of the torso. Any new experiments should provide clear differentiation from prior literature, pointing out specific knowledge gaps and specific improvements to biofidelity of thoracic modeling in a BAPT context. In addition to updated constitutive properties, it is expected that the model developer will provide additional updates to the reference implementation to support biofidelity in a high-energy BAPT use case. Currently, the reference torso has a rigid spine. It is expected that experimental and modeling work performed under this solicitation will evaluate whether the spine should be reparametrized as an articulating and deformable organ, and if so, gather the necessary constitutive response, injury response, kinematic and stress/strain response data from existing literature and/or novel experiments.

3 Administrative Overview

3.1 Request for Proposals

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

3.2 Funding Availability and Type of Funding Instrument Issued

The U.S. Government (USG) currently has available approximately \$850,000 for Fiscal Year (FY) 18. The period of performance is expected to start on March 1, 2018 (subject to change). A near-

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complete prototype must be ready for delivery to the Government by July 31, 2018. Awardees will have until September 30, 2018 to make final minor improvements to the prototype.

As of the release date of this RPP, future year Defense Appropriations Bills have not been passed and there is no guarantee that any additional funds will be made available to support this program. The funding estimated for this RPP is approximate and subject to realignment. Funding of proposals received in response to this RPP is contingent upon the availability of federal funds for this program. Award funding will be structured incrementally and based upon completion of milestones.

It is expected that MTEC will make a single award to a qualified team to accomplish all tasks. However, MTEC may make multiple, individual awards to Offeror(s) to accomplish a subset(s) of the key tasks. However, if an optimal team is not identified, then MTEC may make multiple, individual awards to Offeror(s) to accomplish subset(s) of the key tasks.

If a single proposal is unable to sufficiently address the entire scope of this RPP's technology objectives (outlined in section 5), several Offerors may be asked to work together in a collaborative manner. Therefore, it is highly recommended that only Offerors interested in the potential to collaborate with other Offerors and share data rights submit proposals in response to this RPP.

The Government-selected Research Project Awards will be funded under the Other Transaction Agreement (pOTA) Number W81XWH-15-9-0001 (or subsequent OTAs in support of MTEC) with MTEC administered by the CM, ATI. Strategic oversight for the award(s) supported by this RPP will be provided by the ONR Code 34 Warfighter Performance Department and their support team. The CM will negotiate and execute a Base Agreement with MTEC members. This Base Agreement will be governed by the same provisions as the pOTA between the USG and MTEC. Subsequently, any proposal that is selected for award will be funded through a Research Project Award issued under the Base Agreement. A sample of the MTEC Base Agreement can be found on the MTEC Members-Only website at www.mtec-sc.org.

At the time of the submission, if Offerors have not yet executed a Base Agreement, then Offerors must certify on the cover page of their 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.

Offerors are advised to check the MTEC website periodically during the Proposal preparation period for any changes to the MTEC Base Agreement terms and conditions as well as clarifications found in Frequently Asked Questions (FAQ) responses.

3.3 Proprietary Information

The MTEC CM will oversee submission of Proposals submitted in response to this RPP. The MTEC CM shall take the necessary steps to protect all proprietary information and shall not use such proprietary information for purposes other than the evaluation of an Offeror's Proposal and the subsequent agreement administration if the Proposal is selected for award. An Offeror's submission of a Proposal under this RPP indicates concurrence with the aforementioned CM responsibilities.

Also, as part of MTEC's mission to incorporate philanthropic donations, MTEC frequently makes contact with private entities (e.g., foundations, organizations, individuals) that award grants or otherwise co-fund research, and/or operates in research areas that are aligned with those of MTEC. These private entities (e.g., Bill and Melinda Gates Foundation) may be interested in reviewing certain Proposals within their program areas, allowing opportunities to attract supplemental funding sources. 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 foundations. MTEC Officers and Directors granted Proposal access have signed Non-disclosure Agreements (NDAs) and Organizational Conflict of Interest (OCI) statements. Additionally, these MTEC Officers and Staff represent organizations that currently are not MTEC members, and therefore their parent organizations are not eligible to submit Proposals or receive any research project funding through MTEC. Additionally, all Technical Evaluation Panel participants will agree to, and sign a nonproprietary information and conflict of interest document.

3.4 Offeror Eligibility

Offerors must be MTEC Members in good standing.

3.5 Inclusion of Nontraditional Defense Contractors

Proposals that do not include Nontraditional Defense Contractor participation to a significant extent, or do not propose at least one third acceptable cost sharing, will not be eligible for award. This requirement is a statutory element of the Other Transaction Authority and will be regarded as a pass/fail criterion during the Compliance Screening. Please see the MTEC PPG (Section 3.3.2) and RPP (Section 6), for additional details.

3.6 Nontraditional Defense Contractor Definition

A nontraditional defense contractor is a business unit that has not, for a period of **at least one year prior to the issue date of the Request for Project Proposals**, entered into or performed on any contract or subcontract that is subject to full coverage under the cost accounting standards (CAS) prescribed pursuant to section 26 of the Office of Federal Procurement Policy Act (41 U.S.C. 422) and the regulations implementing such section.

3.7 Nontraditional Defense Contractor 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, the Offeror shall submit Warranties and Representations (see Attachment 2 of the PPG) specifying the critical technologies being offered and/or the significant extent of participation of the nontraditional

defense contractor. The nontraditional defense contractor can be an individual so long as he/she has a DUNS Number and meets the requirements in the Warranties and Representations. The significance of the nontraditional defense contractor's participation must be explained in detail in the signed Warranties and Representations. Inadequate detail can cause delay in award.

Per the DoD OT Guide, rationale to justify a *significant contribution* includes:

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

3.8 Cost Sharing Definition

Cost sharing is defined as the resources expended by the award recipients on the proposed statement of work (SOW). If cost sharing is proposed, then the Offeror shall state the amount that is being proposed and whether the cost sharing is a cash contribution or in-kind contribution; provide a description of each cost share item proposed; the proposed dollar amount for each cost share item proposed; and the valuation technique used (e.g., vendor quote, historical cost, labor hours and labor rates, number of trips, etc.). Cost sharing is encouraged if possible, as it leads to stronger leveraging of Government-contractor collaboration.

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.

See the MTEC PPG for additional details. If the offer contains multiple team members, this information shall be provided for each team member providing cost share.

3.9 Intellectual Property

Intellectual Property (IP) rights for MTEC Research Project Awards will be defined in the terms of an awardee's Base Agreement and resultant Task Orders. MTEC reserves the right to assist in the negotiation of IP, royalties, licensing, future development, etc., between the government and the individual performers during the entire award period.

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. Additionally, MTEC has established two methods of payment to be made to MTEC surrounding the licensing/commercialization of Intellectual Property developed with funding received from MTEC 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.

3.10 Data Rights

The Offeror shall comply with the terms and conditions defined in the Base Agreement regarding Data Rights. **It is anticipated that anything delivered under this proposed effort would be delivered to the Government with Government purpose data rights or unlimited data rights. If this is not the intent, then the Proposal 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

3.11 Expected Award Date

Offeror should plan on the period of performance beginning March 1, 2018 (subject to change). A near-complete prototype must be ready for delivery to the Government by July 31, 2018. Awardees will have until September 30, 2018 to make final minor improvements to the prototype. The Government reserves the right to change the proposed period of performance start date through negotiations via the CM and prior to issuing a Research Project Award.

3.12 Anticipated Proposal Selection Notification

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

4 Proposal

4.1 Proposal

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

The MTEC PPG is specifically designed to assist Offerors in understanding the proposal preparation process. The proposal format provided in the MTEC PPG is mandatory. MTEC will post any general questions received and corresponding answers (without including questioners proprietary data) on the Members-Only MTEC website. The Government will evaluate Proposals submitted and will select Proposals that best meet their current technology priorities using the criteria in Section 6.

4.2 Proposal Submission

Found on the MTEC Members-Only site.

4.3. Submission Format

Found on the MTEC Members-Only site.

5 Proposal Preparation Instructions

5.1 General Instructions

The Technical Proposal and Cost Proposal must be submitted in two separate volumes, and shall remain valid for 180 days unless otherwise specified by the Offeror in the proposal. The Proposal format provided in this MTEC RPP is mandatory and shall reference this RPP number (MTEC-18-04-I-PREDICT). Offerors are encouraged to contact the POC identified herein up until the proposal submission date/time to clarify requirements. Offerors are to propose a Milestone Payment Schedule which should include all significant event/accomplishments that are intended to be accomplished as part of the project, a planned completion date (based on months post award), the expected research funding expended towards completing that milestone, and any cost share, if applicable.

The Milestones and associated accomplishments proposed should, in general, be commensurate in number to the size and duration of the project. A milestone is not necessarily a physical deliverable; it is typically a significant R&D event. Quarterly and final technical reports may be considered deliverables, but they are not milestones. Please include quarterly and final technical reports as part of the Milestone Payment Schedule, without an associated cost.

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

5.2 Technical Requirements

5.2.1 Technology Objectives of RPP 18-04-I-PREDICT

The Proposal will provide a written description of the means and methods that will be used to further develop an existing *in silico* “skin-in” computational finite element model of the Warfighter’s thorax that will predict immediate injury and near term functional incapacitation resulting from exposure to BABT. For the purposes of this solicitation the thorax will be defined as anatomical structures within and including the thoracic wall. It is preferred that an Offeror (i.e., single organization or multi-organizational team) propose solutions to both Tasks 1 and 2 listed below, however, it is acceptable to propose on only one of the two tasks; in other words, a proposal does not have to propose a workplan for all tasks. However, if a single Offeror is unable to propose a technically sound approach to all tasks, it is likely that the Government will require several Offerors to work together in a collaborative manner (including sharing data) to accomplish all tasks as a unified team.

I-PREDICT performers will be expected to meet evolving requirements while leveraging Agile best practices in model development and experimentation including but not limited to; maximize use of existing tissue computational models and validation data where appropriate, ensure model extensibility beyond the use case specified within this RPP, and engage in robust communication between the Government and performers.

At the end of the 6-month period of performance, it is the Government’s desire to demonstrate the use of the I-PREDICT model in a behind armor blunt trauma hazard scenario to accurately predict injury to the thorax and the resulting functional incapacitation. It is expected that the model will meet minimum critical performance standards which will be specified throughout and at the end of the period of performance. These standards will be negotiated with the performers.

The following tasks are not listed in order of importance.

Task 1. Experimental Work in Support of Behind Armor Blunt Trauma to the Thorax (provide detailed costs by task)

To date, much of the injury biomechanics literature has been developed for civilian automotive and aviation safety. Many of the injuries sustained during military service are in vehicle-mounted conditions, including ground and air platforms, while wearing PPE not used in the civilian environment. The severity and high-rate of forces and resulting strain rates on tissues occupies a range from zero to some statistical maximum in a military context, with an as-yet unknown overlap in parameter ranges between civilian vehicle hazard experiments and military vehicle hazard experiments. The current intended use of the I-PREDICT FNC is in support of safer PPE, and therefore, the associated hazard ranges must be appropriate for a military context. Experimentation in support of I-PREDICT will focus on the hazard regimes associated with BABT.

Understanding the bulk constitutive material properties of biological tissue is complex due to the heterogeneity of the architecture at scale. The nature of this dependence is of particular importance in tissue where the structure and mechanical properties directly determine the

physiological behavior, and damage in any structure can induce a behavioral change. Understanding such cause and effect relationships has the potential to enable improved preventative measures to be developed or to inform treatment methods. Therefore, performing measurements with live tissue is critically important in order to draw accurate conclusions.

Much of the tissue-level testing used to parameterize computational models comes from cadaveric tissue, which may not adequately represent the biomechanical response of live human tissue. More biofidelic constitutive properties that better represent living human tissue are needed to support model parameterization. Given the PoP is 6-months, where possible, experimentation in support of I-PREDICT will prioritize non-invasive, non-injurious testing (e.g., MR Elastography) in live humans and/or animals to inform model parameterization and validation.

Special Instruction:

Experimentation is sought as part of the proposal to support model development and validation for behind armor blunt trauma use. Cadaveric tissue testing or others as described above should be performed under physiologic conditions. To avoid unnecessary and expensive duplication of experiments, ranges of forces, strains, or other inputs that are intended to be used in biomechanics experiments should be specified to differentiate proposed research from previously published experiments. Proposals should include information on the thorax hazard regimes typical of BABT and how it overlaps or differentiates from prior research on aviation and automotive safety, with specific citations of prior research and citing specific hazard parameters. Experiments may include constitutive responses, injury responses, and kinematic or stress/strain responses of the thorax under conditions specific to BABT due to high energy lethal projectiles, with resulting high energy transfer through body armor and high tissue strain rates. It is expected that performers will work with ONR to formulate a final set of experiments to inform the development and validation of the I-PREDICT FNC. Proposals should also include a description of the Offeror's history and success of working collaboratively within a multi-organizational team to deliver a whole-body model of the human body or sub-region that is responsive to injurious forces.

Task 2. Thorax Model Developer (provide detailed costs by task)

The model developer will be responsible for the development and validation of the model. (Please see "additional points of consideration" for more information on model validation.) The model developer will receive the government-owned torso model (see section X.X.X for more details), a previously developed finite element model of the thorax and abdomen, and will be expected to update the model via reparameterization to support a BABT use case involving high energy lethal projectiles with resulting high energy transfer and tissue strain rates. The reference model torso has a rigid spine. The model developer will consider whether the spine model will be reparametrized as articulating and deformable to supply needed biofidelity for high energy BABT. The model developer, in collaboration with the experimental performers, will demonstrate valid input of applied forces that account for functional fit and dissipative effect of protective operation of body armor about the thorax. The model developer is expected to ensure that interfaces between the sub-components are compatible and avoid unnecessary computational

cost associated with computationally expensive contacts. The model developer will work closely with experimentalists to align experimental needs to those of the model, to incorporate experimental data into the model, and to ensure that any validation simulations match the experimental tests as closely as possible. Model development should not inhibit the ability of the model to be morphed to different anthropometries in the future.

Special Instruction:

Proposals are requested addressing development of the thorax model in support of injury and incapacitation prediction due to BABT involving high energy lethal projectiles. Proposals for the role of Model Developer should address the technical items below: (1) Solver and (2) Verification, Validation (V&V). Proposals should also include a description of the Offeror's history and success of working collaboratively within a multi-organizational team to deliver a whole-body model of the human body or sub-region that is responsive to injurious forces.

Additional Points of Consideration: When responding to this RPP, especially Task 2 described above, please take into consideration the following two additional major points and the optional point.

(1) Solver

The I-PREDICT FNC will be constructed and run in the LS-DYNA solver.

Special Instruction:

Proposals should address the Offeror's experience using LS-DYNA for human body modeling. Proposals should also address Offeror's access to LS-DYNA site and high performance computing licenses required for supporting construction of and simulations using the I-PREDICT FNC.

(2) Verification and Validation for Behind Armor Blunt Trauma Injuries to the Thorax and associated Functional Incapacitation.

It is expected that the I-PREDICT FNC will be quantitatively validated against experimental data obtained in Task 1 and additional experimental data found in the literature to support its use in prediction of BABT injuries to the thorax and the associated functional incapacitation. These data shall be separate from those used to create models and constitutive material equations, instead operating at the scale of the entire torso and involving kinematic and/or stress/strain time-history data. Further, objective validation measures, such as the International Organization for Standardization (ISO) standard ISO/TS 18571:2014¹, will be used to avoid human biases validation against real-world human injury data sources, such as autopsy reports from military members (e.g., Armed Forces Medical Examiner), surface wound mapping model, Technical Support Working Group (TSWG), Counter-Terrorism Technical Support Office (CTTSO) will be necessary.

¹ <https://www.iso.org/standard/62937.html>

According to MIL-STD-3022², “Department of Defense standard practice documentation of verification, validation, and accreditation (VV&A) for models and simulations,” the M&S VV&A process should produce each of the following documents: 1) Accreditation plan, 2) V&V plan, 3) V&V report, and 4) Accreditation report. MIL-STD-3022 provides templates for each document. It is expected that program performers will work with ONR to formulate a complete V&V plan for the I-PREDICT FNC.

Special Instruction:

Any experience performing verification and validation is requested as part of the proposal. Any experience working within the framework of MIL-STD-3022 and DoD Instruction 5000.61³, “DoD Modeling and Simulation (M&S) Verification, Validation, and Accreditation (VV&A)” is requested. The I-PREDICT program’s goals do not include the development of novel computer-aided design (CAD) and/or finite element models (FEMs) of body armor or ballistic projectiles, nor will such products be provided to performers by the government. Any validation activities must identify and source ready-made CAD and/or FEMs of body armor and projectiles.

(3) Optional: Variation in anthropometry.

As outlined in section 2, it is expected that the resulting I-PREDICT computational model will allow model morphing that will permit the representation of multiple anthropometries (e.g., 5th female and 95th male). Additional tasking may be added, depending on timeline and availability of funding, for the model developer to provide a mid-sized male and 5th percentile female model. Offerors who are proposing against Task 2 and capable of delivering both a mid-sized male and 5th percentile female model in addition to the tasking outlined above, should consider briefly outlining their expertise and methods.

Optional Task 3. Abdominal and Lower Back Experimental Work and Model Development (do not provide costs at this time)

Although responses to this solicitation should focus on the experimental work and model development related to the thorax as outlined above, consideration will be made, depending on timeline and availability of funding, for both experimental and computational modeling work related to the abdomen and lower back for BABT injuries and associated functional incapacitation. Offerors who are capable of addressing the abdomen and lower back, along with the thorax, should consider briefly outlining their expertise and methods.

5.2.2 Technology Objectives of Potential Follow-on Work beyond the Scope of this RPP

The intent of this RPP 18-04-I-PREDICT is to evaluate and award Tasks 1 and 2 described in section 5.2.1; therefore, all proposals submitted under this RPP must propose solutions to either Task 1 or 2 or both. This section is intended to provide context so the Offeror is aware of potential work that could follow-on after the completion of Tasks 1 and 2. ***The Offeror does not need to price or provide details on how they would complete this follow-on work, but they should take this***

² <http://www.acq.osd.mil/se/pg/guidance.html>

³ http://www.dtic.mil/whs/directives/corres/pdf/500002_dodi_2015.pdf

information into consideration to ensure that the proposed work for Tasks 1 and 2 provides placeholders and interfaces that have the potential to meet the full description provided herein.

MTEC will consider the method of soliciting and awarding this follow-on work at the completion of Tasks 1 and 2.

For this subsequent work, it is expected that a **Technical Committee** consisting of representatives from the various Awardees/Performers will be created. The Technical Committee will be responsible for meeting regularly and reporting progress to ONR. At a minimum, the Technical Committee will consist of regional body part model developers, a whole-body model Integrator, and experimentalists. Other Technical Committee positions may be considered, such as pre- and post-processing tool developers and additional experimentalists. A similar approach was implemented during the development of Global Human Body Modeling Consortium (GHBMC) models.

Potential Follow-on Task 3. Experimental Work in Support of I-PREDICT (do not provide costs at this time)

Additional experimentation beyond Tasks 1 and 2 may be requested as part of future RPPs. Cadaveric or other tissue tests are expected to be performed under physiologic conditions, where applicable. Biomechanics experiments should be described in sufficient detail to differentiate research from previously published and cited experiments.

Potential Follow-on Task 4. Regional Model Developers (do not provide costs at this time)

Regional model developers may be responsible for the development and validation of additional regional models including and beyond those developed in Tasks 1 and 2. Regional model developers will receive high-fidelity meshed anatomy from the whole-body model integrator and access to the CAD anatomy used by the program. Regional model developers will derive multiple reduced-fidelity regional models with discrete fidelity levels. These models with varied fidelity will then be subjected to material property parameterization and model validation by the regional model developer, based on biomechanical parameters available from published literature, and/or from experimental biomechanics work performed under the program. If changes are required to the mesh or anatomy, regional developers will work closely with the whole-body model Integrator (see below) to ensure that interfaces between the regions are compatible and avoid unnecessary computational cost associated with computationally expensive contacts. It is also anticipated that regional developers will be tasked with secondary validation of other regions not developed by them, time and funding permitted. Regional model developers will work closely with experimentalists to align experimental needs to those of the regional model and to ensure that validation simulations match the experimental tests as closely as possible.

Potential Follow-on Task 5. Integrator (do not provide costs at this time)

The whole-body model Integrator will be responsible for providing the whole-body mesh to the regional model developers, the technical integration of the regional model components into the

whole-body model, and validation of the whole-body model. Delivery of the completed model to ONR at the end of the period of performance will also be the responsibility of the Integrator. The whole-body model Integrator will be responsible for the creation and management of interface control documentation between the various regional models and pre-processing tools. The Integrator will work closely with experimentalists to align experimental needs to those of the whole-body model and to ensure that validation simulations match the experimental tests as closely as possible. If required, the Integrator will incorporate findings from the experiments performed as part of this project to better parameterize the model. The Integrator will also work closely with the developers of the tools for variations in anthropometry and the pre- and post-processing tools to ensure the tools are compatible with the model.

Potential Follow-on Task 6. Computer Aided Design (CAD) Anatomy (do not provide costs at this time)

Open-source reference digital anatomy for a representative 50th percentile for height and weight adult male and a 50th percentile for height and weight adult female human body typical of military service will be identified and/or developed, modifying or integrating existing reference anatomy where appropriate.

The program will prioritize existing CAD anatomy that can be procured by the project, over development of a new CAD anatomy, assuming there are no or limited restrictions on its use. Priority will be given to CAD anatomy offerings that have no restrictions on use, or the least restrictions on use. It is expected that the whole-body CAD anatomy should include the quantity and type of anatomical components at least equivalent to those in the Global Human Body Modeling Consortium (GHBMC) 50th percentile seated male anatomy⁴ and the Total Human Model for Safety (THUMS)⁵, including but not limited to the complete skeleton, complete musculature, all major internal organs, blood vessels and nerves that provide structural integrity, and ligament and cartilage structures. Proposals should include information on the standard format that will be used to supply the CAD anatomy.

Potential Follow-on Task 7. Variations in Anthropometry (do not provide costs at this time)

The I-PREDICT FNC will allow users to morph the whole-body model to different anthropometric dimensions corresponding to typical military personnel (due to military physical requirements and standards), and will allow the user to reposition the whole-body model to assume different postures (e.g., prone, crouched, seated, and standing). These capabilities will be integrated into the pre-processing tools outlined below in “Potential Follow-on Task 8. Pre- and Post-Processing Tools.” However, the developer of this tool will be responsible for ensuring compatibility with the model, LS-DYNA software, and the pre- and post-processing tools. It is expected that *existing*

⁴ Gayzik et al. Development of a Fully Body CAD Dataset for Computational Modeling: A Multi-modality Approach. *Ann Biomed Eng.* 2011. 39(10): 2568-2583

⁵ Iwamoto et al. Development and Validation of the Total Human Model for Safety Toward Further Understanding of Occupant Injury Mechanisms in Precrash and During Crash. 2015. 16:sup1, S36-S48

and/or new technologies and procedures that provide morphing and posturing capabilities will be sought. These capabilities are expected to allow the model to meet a wide range of anthropometries and postures. However, the technology should allow specific anthropometries of 5th percentile female, 50th percentile male, and 95th percentile male anthropometries (for height and weight). Standing, seated, and prone postures are desired. Methods for altering anthropometry and posture should demonstrate preservation of the accuracy of meshed support and internal organ structures and contact appositions.

Potential Follow-on Task 8. Pre- and Post-Processing Tools (do not provide costs at this time)

The expected user of the I-PREDICT FNC will have subject matter expertise in human body finite element modeling. As much as is realistic, however, model set-up and injury and incapacitation prediction should be handled semi-autonomously.

Pre-processing tools will provide user-level control of capabilities outlined above in “Potential Follow-on Task 7 - Variations in Anthropometry.” Pre-processing tools should enable a workflow that begins with a highest fidelity 50th percentile male or female warfighter in a standing posture. The user may then switch out any of the regional body part models for any of the alternate lower-fidelity regional body part models provided by the regional modelers. Interface definitions will be provided by the Integrator and the pre-processing tools will implement the interfaces. An additional step may involve the user further modifying regional body part fidelity. Following fidelity manipulations, the user may then employ capabilities for altering the morphology of the model to desired anthropometry. The user may then employ additional software capabilities to modify the posture of the whole-body model. After all manipulations in this sequence, the model will be saved as an LS-DYNA compatible model file.

Post-processing tools should include the ability to extract injury and incapacitation risk from standard physical parameters derived from simulations such as stress, strain, velocity, and strain energy from the tissue scale to the whole-body scale. Developers of the pre- and post-processing tools will work closely with the Integrator on the development but will be responsible for ensuring compatibility with the whole-body model and LS-DYNA software.

Additional Points of Consideration for Potential Follow-on Tasks:

(1) Interfaces Between Component Pieces

Creating a complex model of the human body constructed of component level models (e.g., thorax, head, and abdomen) requires that significant consideration be given when designing the interfaces between the component level models to avoid excess computational expense, while ensuring that the model accurately represents the response of the human body to hazards. Interfaces between regional models will be controlled by the Integrator who will work with the regional developers to ensure all needs are being met. It is expected that any abdomen and thorax model that is developed under this solicitation will include processes to avoid computationally expensive interfaces between regional models and components within a

regional model and include a method of validating that the forces and reaction to those forces are accurately transferred between model components, considering the tradeoffs between computation, cost, and accuracy.

(2) Variation in Fidelity

Simulations of the human biomechanical response to dynamic hazards are computationally expensive. Full body simulations can be excessively long and require the use of high performance computing resources. Scientific methods for the judicious reduction in fidelity (e.g., mesh density, different material models, contact stiffness, and deformable vs. rigid bodies) of the I-PREDICT FNC in areas of the body that are of little interest to the specified hazard scenarios, or are not typically injured as part of the specific hazard scenario, may result in improved run-time with minimal effect on the accuracy of the results of interest.

Such capabilities may be integrated into the pre-processing tools to allow an end user to manipulate fidelity of the resulting models. Such manipulations are in addition to the selection of a baseline model.

5.3 Government Furnished Resources

Offeror(s) who are selected to receive project awards may assume that the Government will make available the following materials:

1. I-PREDICT Reference Torso Model

For purposes of this solicitation, the I-PREDICT Reference Torso Model is a finite element model of the human torso that was originally developed for non-lethal impactors (e.g., sandbags, rubber bullets, etc...). This model was developed for LS-DYNA and receives a finite element model of the impactor as an input. The anatomy of the model was rendered from the visible human project⁶ and includes the: ribs, spine, sternum, lungs, heart, liver, spleen, stomach, diaphragm, surrounding musculature, and the skin. Material definitions were taken from published literature and the portions of the torso were validated against a series of experimental tests.

Awardees will receive access to the current version of the I-PREDICT Reference Torso Model which includes, (1) locations of nodes of a finite element mesh, (2) interconnections among the nodes to define elements, (3) definitions of material properties of elements, (4) definitions of contact characteristics of elements, and (5) associated documentation. A licensing agreement will be provided stipulating clear guidelines on the use of the model, during and after the period of performance.

5.4 Preparation of the Proposal

The proposal format provided in the MTEC PPG is mandatory. Proposals shall reference this RPP number (MTEC-18-04-I-PREDICT). The Technical Proposal and Cost Proposal must be submitted

⁶ https://www.nlm.nih.gov/research/visible/visible_human.html

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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 full proposal should include the following:

- **Technical Proposal submission:** one signed Technical Proposal (.pdf, .doc or .docx). The Technical Proposal must include the requested information in the format provided in the PPG. In addition, the following sections should be included in the technical proposal:
 - **Progress:** The Offeror will describe the milestones that will be used to measure progress during the period of performance and describe the oversight managerial methods that will be employed to maintain a quality and timely performance.
 - **Relevant Experience:** The Offeror will convey details related to past performance(s) that demonstrate relevance to the scope of the proposed work and build confidence in the team’s capabilities.
 - **Effectiveness (Opportunity and Risk):** The Offeror will identify opportunities (e.g., reduction in cost or schedule, and/or improvement in performance) and risks within each appropriate project Cost, Schedule, Performance measure of effectiveness. This should include a mitigation plan for each identified risk item.
 - **Data Rights Assertions:** The Proposal will identify any and all proprietary and/or intellectual property involved in the efforts and any associated restrictions that may possibly affect the Government’s use of the property in any way whatsoever. Describe your pathway to developing this into a product that can be used by the DoD and other potential customers (if applicable). Include relevant information about existing royalty agreements.
 - **Technical Collaboration:** Use the following table to highlight all past (within the last 10 years), current, and pending DoD grants, contracts, or awards related to human body experimental and computational modeling and simulation work in which the Offeror worked as a member of a collaborative team. The Offeror may extend the number of rows in the table as needed to provide sufficient space to list 10 years of awards. This table will not count against the stated white paper proposal page restrictions.

Project Title	Contract/Grant number	Government Contact (name, email, & telephone)	Point of	Period of Performance

- **Statement of Work/Milestone Payment Schedule:** one Word (.docx or .doc). The Offeror is required to provide a detailed SOW/Milestone Payment Schedule using the format provided herein (Attachment A). The Government reserves the right to negotiate and

revise any or all parts of SOW/Milestone Payment Schedule. Offerors will have the opportunity to concur with revised SOW/Milestone Payment Schedule as necessary.

- **Cost Proposal by Task submission:** one Word (.docx or .doc) or PDF file for Section I: Cost Proposal Narrative (see Attachment 1 of the PPG) required. Separately, Section II: Cost Proposal **by Task** Formats either in Excel (.xlsx or .xls) or PDF format is required.
- **Warranties and Representations:** If Nontraditional Defense Contractor participation is proposed, Warranties and Representations (see Attachment 2 of the PPG) are required. One Word (.docx or .doc) or PDF file that contains all Warranties and Representations is required.
- **Royalty Payment Agreement or Additional Research Project Award Assessment:** Each Offeror will select either the MTEC Additional Research Project Award Assessment Fee or the Royalty Payment Agreement (available on the MTEC members only website), **not both**, and submit a signed copy with the proposal.

Evaluation: The Government will evaluate and determine which proposals to award based on criteria described in **Section 6, Selection** of this RPP. The Government reserves the right to negotiate with Offerors.

5.5 Cost Proposal

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

Each cost should include direct costs and other necessary components as applicable, for example, fringe, General & Administrative Expense (G&A), Facilities & Administrative (F&A), Other Direct Costs (ODC), etc. Offerors shall provide a breakdown of material and ODC costs as applicable.

5.6 Proposal Preparation Costs

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

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

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

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

For example, the clinical studies under this RPP shall not begin until the USAMRMC Office of Research Protections (ORP) provides authorization that the research may proceed. The USAMRMC ORP will issue written approval to begin research under separate notification. Written approval to proceed from the USAMRMC ORP is also required for any Research Project Awardee (or lower tier subawards) that will use funds from this award to conduct research involving human subjects. Offerors must allow at least 30 days in their schedule for the ORP review and authorization process.

6 Selection

The CM will conduct a preliminary screening of submitted proposals to ensure compliance with the RPP requirements. Proposals that do not meet these requirements may be eliminated from the competition or additional information may be requested. One of the primary reasons for non-compliance or elimination during the initial screening is the lack of significant nontraditional defense contractor participation or cost share (see RPP Section 2.6). The Cost Sharing/Nontraditional Contractor determination will be made as shown in Table 1:

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

Following the preliminary screening, the Government sponsor will perform proposal source selection. This will be conducted using the evaluation factors detailed below. 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)*

6.1 Proposal Evaluation Process

Qualified applications will be evaluated by a panel of subject matter experts who will make recommendations to a Source Selection Authority appointed by ONR.

This process may involve the use of contractors as SME consultants or reviewers. Where appropriate, the USG will employ non-disclosure-agreements to protect information contained in the RPP as outlined in Section 2.3.

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

The evaluation factors and evaluation criteria are described below.

6.1.1. Evaluation Factors

1. Technical Approach (65%)
2. Cost/Price (25%)
3. Potential for Transition and Commercialization (10%)

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

Table 2 explains the adjectival merit ratings that will be used for the Technical Approach Factor, and Potential for Transition and Commercialization factor.

TABLE 2- GENERAL MERIT RATING ASSESSMENTS
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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.

6.1.1.1 Evaluation Factor 1. Technical Approach

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

The Offeror’s proposed solution will be assessed for the likelihood of successfully achieving the requirements of the technology of interest as defined in Section 5.2 above. The likelihood of success will be determined by considering the soundness and clarity of the technical approach. Additional consideration will be given to the degree to which any preliminary existing data supports the proposed project plan and the suitability of the proposed statistical plan. The SOW should provide a succinct approach for achieving the project’s objectives. The SOW will be evaluated for how well the rationale, objectives, and specific aims support the proposed research. The effort will be assessed for the extent to which the solution is technologically innovative and how the proposed deliverable advances the TRL Military relevance is a critical component of proposal submission. This relevance includes the health care needs of military Service members, Veterans, and/or other Military Health System beneficiaries and the extent to which the proposal offers a joint Service solution. A description of the project team’s expertise, key personnel, and corporate experience should demonstrate an ability to execute the SOW.

6.1.1.2. Evaluation Factor 2. Cost/Price

The Cost/Price area will receive a narrative rating to determine whether costs are realistic, reasonable, and complete.

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The MTEC CM will evaluate the estimated cost proposed by the Offeror for performing all requirements outlined in this RPP and the MTEC PPG. Evaluation will include analysis of the proposed cost together with all supporting information. The Offeror's cost and rationale will be evaluated for realism, reasonableness, and completeness. If a proposal is selected for award, the MTEC CM will review the original cost proposal and the Offeror's response to a Proposal Update Letter, if applicable. The MTEC CM will request additional information or clarification as necessary. The MTEC CM will assess the reasonableness and completeness of the cost estimates and then provide a formal assessment to the Government. The Government will review this assessment and make the final determination that the negotiated project value is fair and reasonable.

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

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 schedule proposal.

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

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

b) 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.

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.

6.1.1.3. Evaluation factor 3: Potential for Transition and Commercialization.

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

The Offeror's proposal will be assessed for:

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

6.2 Best Value

The Government will conduct the source selection and MTEC CM will award the projects in Best Value sequence. If applicable, the Government will invoke a best value process to evaluate the most advantageous offer by considering and comparing factors in addition to cost or price. Based on the results of the Technical Approach 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.

6.3 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.

7 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 Proposal the Government and the MTEC CM will not discuss evaluation/status until the source selection process is complete.

8 Acronyms/Abbreviations

AAR	After Action Report
ATI	Advanced Technology International
AV	Architecture View
CDD	Capability Development Document
CM	Consortium Manager

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CMA	Consortium Member Agreement
COCOM	Combatant Commands
CPD	Capability Production Document
CV	Capabilities View
DoDAF	Department of Defense Architecture Framework
FAQ	Frequently Asked Questions
F&A	Facilities and Administrative Costs
FY	Fiscal Year
G&A	General and Administrative Expenses
GPM	Global Patient Movement
IP	Intellectual Property (e.g., patents, copyrights, licensing, etc.)
JCIDS	Joint Capabilities Integration and Development System
JETS	Joint Training and Evacuation Transport Simulation
JPM	Joint Patient Movement
KSA	Key Systems Attribute
KPP	Key Performance Parameter
LMS	Learning Management System
ISS	Instruction Support System
LVCG	Live, Virtual, Constructive, Gaming
M	Millions
MeTER	Medical Training Evaluation and Review
MSTC	Medical Simulation Training Centers
mSTE	medical Simulation Training Environment
MT-C2	Medical Training – Command and Control
NDA	Nondisclosure Agreement
OCI	Organizational Conflict of Interest
ODC	Other Direct Charges
ONR	Office of Naval Research
ORP	Office of Research Protections, USAMRMC
OV	Operational View
pOTA	Prototype Other Transaction Agreement
POC	Point-of-Contact
POD	Point of Demand
PPE	Personal Protection Equipment
PPG	Proposal Preparation Guide
RPP	Request for Project Proposals
SOW	Statement of Work
SV	Systems View
TRL	Technology Readiness Level
USAF CCATT	US Air Force Critical Care Air Transport Team
USAMRMC	U.S. Army Medical Research and Materiel Command
USG	U.S. Government

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VPS Virtual Patient System

Attachment A: Statement of Work (SOW)

The SOW developed by the Lead MTEC member organization is intended to be incorporated into a binding agreement if the Solutions Brief is selected for award. If no SOW is submitted, there will be no award. The proposed SOW shall contain a summary description of the technical methodology as well as the task description, but not in so much detail as to make the contract inflexible. DO NOT INCLUDE ANY PROPRIETARY INFORMATION OR COMPANY-SENSITIVE INFORMATION IN THE SOW TEXT. The following is the required format for the SOW.

Statement of Work

Submitted under Request for Project Proposal (*Insert current Request No.*)

(Proposed Project Title)

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

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

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

Applicable Documents (*To be determined by the Government based on negotiation of Scope/Project Objective*)

In the event only specific requirements of these documents must be included in the SOW then only these excerpts should be used and should be made into either a clear task statement (if required) or a clear reference statement (if for guidance only and not for contract compliance).

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

State the technology objective in the first paragraph and follow with delineated tasks required to meet the overall project goals. The work effort should be segregated into major phases, then tasks and identified in separately numbered paragraphs (similar to the numbered breakdown of these paragraphs). Early phases in which the performance definition is known shall be detailed by subtask with defined work to be performed. Planned incrementally funded phases will require broader, more flexible tasks that are

priced up front, and adjusted as required during execution and/or requested by the Government to obtain a technical solution. Tasks will need to track with established adjustable cost or fixed price milestones for payment schedule. Each major task included in the SOW should be priced separately in the Cost Proposal. Subtasks need not be priced separately in the Cost Proposal.

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

Results of the technical effort are contractually binding and shall be identified herein. Offerors are advised to read the Base Agreement carefully. Any and all hardware/software to be provided to the Government as a result of this project shall be identified. Deliverables should be submitted in PDF or MS Office format. It must be clear what information will be included in a deliverable either through a descriptive title or elaborating text.

The following information is required:

- Monthly written progress reports (covering cost, schedule, performance, risk & opportunity) project metrics
- The JETS DODAF artifacts are delivered at the end of Phase 1
- The POINTS artifacts are delivered at the end of Phase 2

Milestone Payment Schedule *(To be provided initially by the Offeror at the time of submission. Submitted information is subject to change through negotiation if the Government selects for funding. The milestone schedule included should be in editable format (i.e., not a picture)*

The Milestone Payment Schedule should include all milestone deliverables that are intended to be delivered as part of the project, a planned submission date, the monetary value for that deliverable and any cost share, if applicable. For fixed price agreements, when each milestone is submitted, the MTEC member will submit an invoice for the exact amount listed on the milestone payment schedule. For cost reimbursable agreements, the MTEC member is required to assign a monetary value to each milestone. In this case, however, invoice totals are based on cost incurred and will not have to match exactly to the amounts listed on the milestone payment schedule.

The milestones and associated deliverables proposed should, in general:

- be commensurate in number to the size and duration of the project (i.e., a \$5M multi-year project may have 20, while a \$700K shorter term project may have only 6);
- not be structured such that multiple deliverables that might be submitted separately are included under a single milestone;
- be of sufficient monetary value to warrant generation of a deliverable and any associated invoices;
- include at a minimum Quarterly Reports which include both Technical Status and Business Status Reports (due the 20th of Mar, Jun, Sep, and Dec), Annual Technical

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Report, Final Technical Report, and Final Business Status Report. Reports shall have no funding associated with them.

Milestone No.	SOW Task Number	Significant Event/Accomplishments/Deliverables	Due Date	Total Program Funds	Total Cost Chare	Total Project
1						
2						
3						
N						
Total						

Shipping Provisions *(The following information, if applicable to the negotiated SOW, will be finalized by the Government and the MTEC Consortium Manager based on negotiations)*

- The shipping address is:
Classified Shipments:
Outer Packaging
Inner Packaging

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

- Quarterly Reports – The MTEC research project awardee shall prepare a Quarterly Report which will include a Technical Status Report and a Business Status Report in accordance with the terms and conditions of the Base Agreement. Quarterly Reports shall be submitted by the 25th calendar day following prior calendar quarter close based on the following schedule. (Required)

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

- Annual Technical Report – The project awardee shall prepare an Annual Technical Report for projects whose periods of performances are greater than one year in accordance with the terms and conditions of the Base Agreement. (Required)
- Final Technical Report – At the completion of the Research Project Award, the awardee will submit a Final Technical Report, which will provide a comprehensive, cumulative, and substantive summary of the progress and significant

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accomplishments achieved during the total period of the Project effort in accordance with the terms and conditions of the Base Agreement. (Required)

- Final Business Status Report – At the completion of the Research Project Award, the awardee will submit a Final Business Status Report, which will provide summarized details of the resource status of the Research Project Award, in accordance with the terms and conditions of the Base Agreement. (Required)
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