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Pushing the Acquisition Innovation Envelope at the Office of Naval Research¹

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Abstract

Developing prototypes may require performers, all with different areas of expertise, working together to address the complexity required for a successful development effort. Current Federal Acquisition Regulation (FAR) policy makes it difficult for these collaborations to assemble efficiently. Complex research projects, such as the Office of Naval Research’s Incapacitation Prediction in Expeditionary Domains: An Integrated

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Software Tool (I-PREDICT) project, which seeks to develop a computational model to predict human injury and functional incapacitation as a result of military hazards, often face difficulty when attempting to transition across the “valley of death” from development to adoption. A decision framework was developed and implemented for I-PREDICT to select the appropriate acquisition strategy aligned with the technical needs of the program. A three-phase implementation strategy was also designed, which included the use of an Other Transaction Authority (OTA) and the use of a Technical Committee to promote communication between performers. The resulting decision framework and implementation strategy may be used Navy-wide or across other military Services for R&D programs requiring acquisition flexibility coupled with collaborative technology development. Additionally, the research produced a customizable method for leveraging OTAs as a mechanism for development of complex prototypes depending on disparate kinds and sources of expertise.

Introduction

Background

Developing prototypes in many research & development (R&D) fields may be adequately addressed by one or merely a few performers from industry or academia with few dependencies among them, while other fields require a more widely distributed and collaborative approach. In some cases, several performers with different areas of expertise must work together to address the development of a complex prototype under the guidance of the funding agency. Certain aspects of the Federal Acquisition Regulation (FAR) that are motivated by fair competition requirements may extend time for contract awards, implement inflexible vendor payment processes, and impose a lack of coordination across contracting vehicles between vendors, among other limitations. In addition, when developing an innovative solution, highly complex research projects often face significant difficulties when attempting to transition across the so-called “research valley of death” from development to fielding. The R&D aim of leveraging computational models to predict and prevent battlefield injuries for the warfighter is one of these highly complex research fields that can yield enormous benefits if the contracted performers can collaborate with each other and the funding agency after a solicitation but prior to awards, and if the gap between development and fielding can be bridged.

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 like pressure, stress, strain, or force applied to an organ or tissue. Increasingly, such knowledge is incorporated into scientific simulations that can be run many times over to explore variations in hazards and 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 data. 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 development of personal protective equipment (PPE), safe vehicles, and safe weapons systems, as well as tactics, techniques, and procedures (TTPs) to protect against injury. The development of a high-quality, whole human body computational model of injury is needed to inform such standards and to act as a pivotal part of operational mission planning and risk assessment.



Addressing the Problem

The Future Naval Capabilities (FNC) program was initiated in 2002 by the Department of the Navy to develop a prototype and to transition cutting-edge technologies, at a technology readiness level (TRL) 6, to acquisition program managers within a five-year time frame. Recent changes to the FNC program have placed an increased emphasis on accelerating the transition of Office of Naval Research (ONR) developed solutions to the fleet/force by requiring up-front financial contributions from stakeholders to cover transition costs. Stakeholders commit, via a Technology Transition Agreement (TTA), to develop, transition, and deploy a product delivered by a specific FNC project to the fleet/force. For FNC products that involve a high degree of technical complexity, the use of FAR-based acquisition tools may limit the likelihood of successful product development and/or transition, thus promoting the need to explore non-traditional acquisition methods.

ONR's Code 34 Force Health Protection initiated the Incapacitation Prediction in Expeditionary Domains: An Integrated Computational Tool (I-PREDICT) pre-FNC project to provide an in silico integrated computational model of the warfighter's body to use for injury prevention and treatment, medical response planning, and equipment design including tradeoff analysis, validation, and testing. Warfighter injury in combat and training has high financial and personal costs, and interferes with the ability to complete mission objectives. Accurate prediction of injuries and resulting functional incapacitation under varying hazard conditions would provide the ability to design safe equipment and behavioral practices, and to allow commanders to weigh operational risks during the planning and execution of missions and to allocate resources appropriate to those risks. Faster transition to the field would result in more timely realization of benefit to the warfighter.

Way Ahead

To overcome both the collaboration and transition barriers, R&D programs such as I-PREDICT may leverage Other Transaction Authority (OTA) contractual vehicles to support development of prototype technologies. OTAs are not subject to the FAR, permit the use of commercial-like, negotiated agreements that can be awarded in as little as 90 days, allow highly flexible use of intellectual property, and promote unique public/private partnerships to achieve program objectives. Moreover, upon completion of prototype development, solutions may be transitioned from the OTA vehicle to a sole-source FAR-based procurement production contract which is permissible under 10 U.S.C. 2371b and accelerates the timeline from development to fielding (U.S.C. Code § 2371b).

This paper provides a **description of a decision framework** that was developed to allow full evaluation of technical and acquisition options to meet project needs, building and evaluating potential program strategies, and developing a process for execution of the selected strategy that included leveraging OTA and the Medical Technology Enterprise Consortium (MTEC). The project has executed this decision framework, which is outlined below in later sections of this paper. Additionally, a **three-phase implementation strategy was developed for the execution of the selected project strategy**. The three phases are outlined in the section titled Implementation of the Single Model–Multiple Performer Strategy and have not yet been implemented by the project. The decision framework and three-phase implementation strategy are outlined in Figure 1.



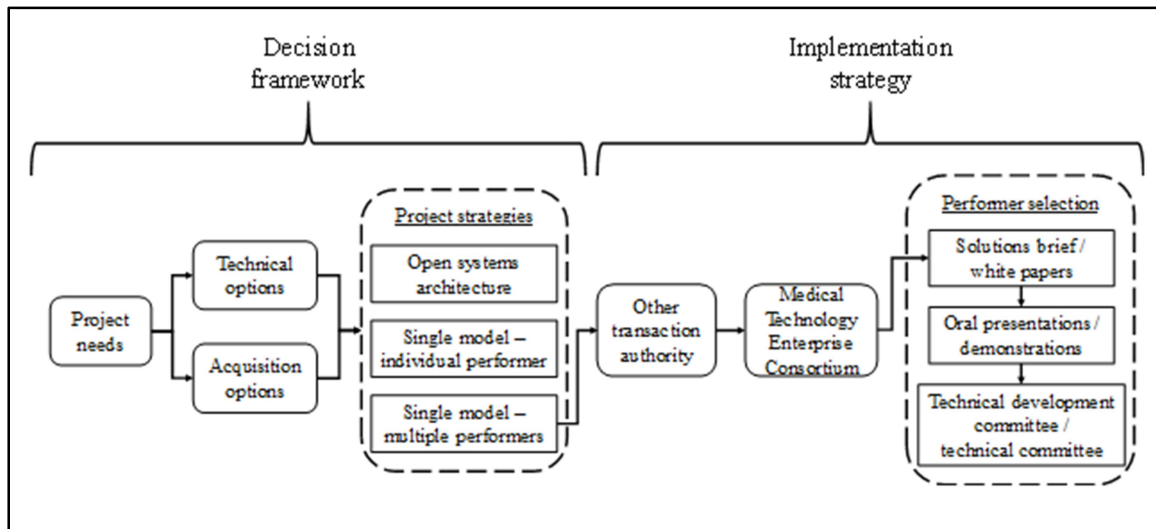


Figure 1. Decision Framework and Implementation Strategy Developed for the I-PREDICT Project

Beyond the decision framework and three-phase selection process, this paper also provides a **tailorable method for leveraging OTAs** as a mechanism for development of prototypes that require many disparate kinds and sources of expertise. This method may be used Navy-wide or across other military Services for any R&D program that requires acquisition flexibility coupled with highly collaborative complex technology development. The implementation strategy grants programs the ability to leverage the innovative Technical Committee (TC) construct, outlined in a later section (Phase III Technical Development Team/Technical Committee Selection), permitting an increased level of collaboration and communication between performers than is typically accessible under the FAR. When the decision framework and the supporting three-phased OTA method are combined, programs can benefit from a unique partnership with performers from industry and academia while streamlining deployment and fielding. As a result, the warfighter may more quickly gain access to effective technological solutions to enhance operations and safety.

Technical Options for I-PREDICT

Considerations regarding the technical options outlined below were essential to ensuring that the I-PREDICT computational model could be successfully developed, and because the technical decisions provide the foundations upon which the modeling capability will be designed, constructed, and employed by the end users. However, decisions regarding each technical option were fraught with complexity because they significantly altered both programmatic scope and the skill sets required to achieve the project goals. The following discussion maps out application and technical needs of the program to specifically illustrate the challenges.

The I-PREDICT program's technical goal is to develop a deformable finite element model (FEM) with detailed human anatomy and accurate human body responses to military hazards (e.g., blunt force impacts and blast shockwave pressure effects). To construct and use a whole-human deformable FEM, several highly interdependent data products are required: **experimentation** is used to gather biomechanical responses of human tissue on scales ranging from small volumes of tissues to organs and large body regions, **digital anatomy** is needed to computationally represent the human body as a group of computer aided design (CAD) components that are converted to finite element mesh components,

interfaces between the components must be defined to mathematically represent how the response of each structure is dependent upon the surrounding structures, management of **anthropometric variability** (different body shapes and sizes) will allow exploration of vulnerability risk dependent on body parameters, creation of additional lower **fidelity** components will result in reduced computational runtimes, and the FEM needs to be **validated** against experimentation at larger scales of organs or large body regions.

A challenge facing the I-PREDICT program is the choice of an optimal set of sources and/or performers for the array of needed data products. For example, if the project decided to pursue multiple CAD anthropometries versus a model that is morphable to multiple anatomical variations, the project would be asking for expertise in CAD development from biomedical imaging data instead of expertise in the development and implementation of morphing technologies. The major topical requirement categories identified for this project where technical options exist are (1) biomechanics **experimentation** in support of model development, (2) software used to simulate the physics (commercial equation **solver**), (3) generation of **digital anatomy** including CAD and subsequent finite element meshing, (4) management of **anthropomorphic variability**, (5) mathematical **interfaces** between component body structures, (6) deliberate variations in component **fidelity**, (7) verification, **validation**, and accreditation (VV&A) of models based on experimental biomechanics, and (8) **pre- and post-processing tools**. The options are described in greater detail below.

Experimentation

Computational models of human injury require experimental validation datasets at a succession of anatomical scales to calibrate and validate biomechanical response properties of the model. These involve small-volume tests of homogeneous tissue types (e.g., liver, muscle, cortical bone), isolated anatomical structure tests (e.g., segments of tendon or ligament, humerus, clavicle), or large-scale tests such as cadaver crash tests using crash sleds, impact pendulums, and/or blast tubes. Biomechanical responses may include measurement of physics parameters such as stress, strain, and force relevant to tissue injury, collected using precision material testing systems. Analysis of movement corridors for whole-body responses to stimuli may calibrate such global parameters as kinematics, and are typically measured with precision high-speed video recording of landmarks and load cells. Ideally, support for experimental decisions should be motivated by knowledge of the military hazard environment, with specific references to experimental data from hazard environments. Biomechanical experiments performed under the I-PREDICT project should also primarily be in support of anatomical components that are most frequently injured during the hazard conditions prioritized by the project, and use cases outlined by I-PREDICT stakeholders and end-users. Determining the appropriate types and quantities of experimental test is necessary to the successful parameterization and validation of the I-PREDICT model. Three technical options were identified: (a) Government provided methodology in which Government would dictate the experiments, (b) performer developed methodology where the performers indicated the experiments they wanted to perform, and (c) a combination approach where both the Government and performers were involved in collaborative decision-making.

Solver

There currently exist several software systems (equation solvers) that are used to mathematically calculate the response of the human body to dynamic hazards. Examples of some of the most prominent solvers include LS-DYNA, Abaqus Explicit, Velodyne, CTH Sandia Shock Wave Physics, and CoBi. These solvers use numerical techniques to calculate a variety of physical variables (e.g., stress, strain, strain rate, and flow rates) within the human body at discrete time points following the onset of the hazard. The finite element



analysis method, the most common method used to study human injuries from blunt impact hazards, represents small physical volumes of material, each referred to as a finite element, with a simple equation. A finite element solver then creates a system of these equations for an entire physical structure of coupled finite elements that are all solved simultaneously over discrete time steps. Selecting the appropriate solver was necessary to ensuring compatibility between the I-PREDICT model sub-components and between the I-PREDICT model and other computational models such as vehicles. Three technical options for selecting a solver were identified: (a) solver independence where multiple solvers would be able to be used simultaneously, (b) a Government-selected solver, and (c) a performer-selected solver.

Anatomy

CAD anatomy is required to accurately model the response of the entire human body to a military hazard. The CAD anatomy is essential because it provides the bounding box for modelers to create not only individual anatomical component models (e.g., liver, spleen, ribs) but also to model the interactions between anatomical components. Although multiple CAD anatomies exist that could be purchased by the project, typically, licenses restrict the distribution of any models developed from them. Therefore, there were two options the project could pursue for obtaining CAD anatomy: (a) a Government-provided CAD and (b) a performer-provided CAD.

Anthropomorphic Variability

It is well known that variations in anthropometry and posture can influence the risk of sustaining injuries. Accurately representing these variations is paramount to understanding how injury risk across the entire representative warfighter population ought to influence design decisions or mission planning. Therefore, the I-PREDICT FNC must be able to represent warfighters of differing anthropometries. As was outlined above in the introduction to the technical options, there were two technical options the project can use to represent multiple anthropometries and postures: (a) development of multiple CAD anatomies that represent multiple body shapes, sizes, and genders in multiple postures; and (b) morphing a single model to multiple anthropometries and/or postures.

Interfaces Between Component Pieces

The whole human body model is constructed of multiple component level models (e.g., heart, lungs, vessels, rib bones), requiring 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 the hazard. These interfaces represent the most computationally expensive portion of the simulation. However, models can be constructed to minimize these types of interfaces. Two technical options were identified to address model component interfaces: (a) the development of interface standards that explicitly define the interfaces between the anatomical component pieces and (b) allow the performers to define the interfaces.

Variation in Component Fidelity

Simulations of the human response to dynamic hazards are computationally expensive, with typical full body simulations taking between 12-48 hours using high performance computing (HPC) resources. To achieve model outputs in a more timely manner, recent work has focused on reductions in fidelity of models, or of selected model components. Allowing for the judicious reduction in fidelity of the I-PREDICT FNC in areas of the body that are of little interest to specific hazard scenarios, or are not typically injured as part of the hazard scenario, may result in improved run-time with minimal effect on the accuracy of the results. The project identified two technical options to address deliberately



varied fidelity of model components: (a) the development of fidelity standards that explicitly define discrete fidelity levels of the anatomical component pieces, including regional components (e.g., thorax, abdomen) and more detailed components (e.g., blood vessels, bones, nerves); or (b) performer-defined fidelity levels.

Verification, Validation, and Accreditation

According to DoD Instruction 5000.61, *DoD Modeling and Simulation (M&S) Verification, Validation, and Accreditation (VV&A)*, it is DoD policy that (1) models, simulations, and associated data used to support DoD processes, products, and decisions shall undergo verification and validation (V&V) throughout their life cycles; (2) models, simulations, and associated data used to support DoD processes, products, and decisions shall be accredited for an intended use; and (3) VV&A results shall be documented and made accessible to the DoD Components, other Government agencies, and non-Governmental activities, as applicable and in accordance with DoD Directive 8320.02, *Data Sharing in a Net-Centric Department of Defense*.

Initiation of the VV&A process early in the project will help to ensure model accuracy and thoroughness, and assist in rapid fleet integration, as much of the necessary work will already be underway. As part of the plan, V&V should be performed throughout the period of performance so that required knowledge gaps can be filled, thus minimizing additional labor needed for FNC deployment to the fleet. The project identified four technical options for V&V: (a) Government develops the V&V plan and executes all of the V&V; (b) developer-initiated V&V in which the model developer(s) would be responsible for creating their own V&V plan and executing the V&V on the model(s) they are developing; (c) alternate developer V&V where V&V of the model components and whole-body model are executed by performers who did not develop the models being tested; and (d) combination V&V where the project would pursue a mixture of Government V&V, developer V&V, and alternate developer V&V.

Pre- and Post-Processing Tools

Pre- and post-processing tools are used to prepare a human body model for specific simulations and to gather outputs following the simulations. Pre-processing tools may include selection of model components, integration of model components via interfaces into a whole human body model, morphing the model to desired anthropometric parameters, altering the posture of the model, and deliberately varying the fidelity of certain model components. Post-processing tools should include the ability to extract injury and incapacitation risk from standard physical parameters such as stress, strain, velocity, and strain energy. The project identified two technical options for the development of pre- and post-processing tools: (a) Government-provided tools where the Government would develop the pre- and post-processing tools and (b) performer-developed tools.

Acquisition Options for I-PREDICT

Considerations regarding the acquisition options for I-PREDICT were critical to ensure that the appropriate technical requirements could be achieved. The technical options, described previously, have several inherent impacts on the acquisition options that may be selected. For example, if an existing contract vehicle such as a GSA schedule were to be chosen, subject matter expertise would be limited to those on that particular contract vehicle who may not possess the depth and breadth of skills required. Likewise, if the most flexible intellectual property approach isn't open and competitive, it would hamper the ability for the model to have free communications between the relative component pieces. In support of these types of concerns, the consideration of acquisition options and their potential impact on available technical options was paramount. As a result, the project



examined several acquisition options that could be leveraged to help build the overall project strategy for I-PREDICT. The major topical categories identified for this project where acquisition options exist are (1) leadership structure, (2) contracting approach, (3) source-selection/evaluation approach, (4) incentive approach, and (5) intellectual property approach. Each of these options is defined below and is later incorporated in the Project Strategies section.

Leadership Structure

Quality project leadership is imperative to delivering a technically sound solution such as the I-PREDICT FNC. There are several leadership structures that have been used to create whole human body models, many of which focus upon the need for collaboration. The Total Human Model for Safety (THUMS) was created independently by Toyota Central R&D Labs. Other whole human body models, including the Human Model for Safety (HUMOS) and the Global Human Body Models Consortium (GHBMC), have used a consortium of model developers to create their whole human body models. Within the GHBMC program, technical leads were assigned to each body region with an overall technical lead responsible for the whole program. For I-PREDICT, there were four leadership structure options that were considered:

- *Government integration with multiple contracts:* In this approach, the Government will be responsible for integrating model components created by the performers under contract into one cohesive model. This provides additional assurances that the I-PREDICT FNC meets the needs of the Government stakeholder-defined use cases.
- *Industry/academia integration with multiple contracts:* In this approach, a designated performer will be responsible for integrating model components created by the other performers under contract into one cohesive model. This allows the project to leverage existing subject matter expertise and removes Government burden.
- *Industry/academia integration and development:* In this approach, a single performer will be responsible for creating the model components and integrating the model components into one cohesive model, potentially subcontracting and supervising components of the modeling. This allows performer flexibility to alter model construction during the period of performance.
- *Technical committee (TC):* In this approach, the Government will assume the management and administration of a TC, including standing up the committee and ensuring that the committee meets project goals. Technical directors will be assigned for each body region who are responsible for the experimental work and model component creation within that body region. The integrator will be a separate performer and part of the TC. In addition, the TC is structured to allow input from consultation with Government advisors and SMEs. This approach allows the project to leverage expertise across industry and academia while promoting communication among performers, and has been used successfully to create the GHBMC model.



Contracting Strategy

The contracting approach provides the rationale for the desired contract vehicle type chosen to acquire integration services, model components, CAD anatomy, and V&V for the I-PREDICT project. Contracting strategies to be considered may include those which are FAR-based (Federal Acquisition Regulation) and non-FAR-based (such as Other Transaction Authority or OTA). There were five contracting approaches evaluated for use for I-PREDICT:

- *Indefinite delivery/indefinite quantity (ID/IQ) contract:* Indefinite delivery, indefinite quantity contracts provide for an indefinite quantity of services for a fixed time. Awards are usually for base years and option years. The Government places delivery orders (for supplies) or task orders (for services) against a basic contract for individual requirements. Minimum and maximum quantity limits are specified in the basic contract as either number of units (for supplies) or as dollar values (for services). Each time a requirement under the scope is identified, individual delivery orders or task orders require a separate contracting action beyond the initial base contract award (GSA, 2017b).
- *C-Contract:* General term for contracts of all types except basic purchasing agreements, basic ordering agreements, indefinite delivery contracts, facilities contracts, sales contracts, and contracts placed with or through other Government departments or agencies or against contracts placed by such departments or agencies outside the DoD (Acquisition Guides, n.d.).
- *Other Transaction Authority (OTA)/Other Transactions (OTs):* OTs are legal binding agreements between the U.S. Government and industry, including traditional and non-traditional Government contractors, small businesses, and academia. Because they are not subject to the FAR, OTs are, by design, more flexible and responsive to atypical Government procurement requirements. Indeed, Congress provides the authority in recognition that, from time to time, boilerplate procurement methods are at odds with the Government's need to innovate. Consequently, OTs are primarily associated with some form of research, development, test, and evaluation (RDT&E; Arendt et al., 2018). The common theme of OT use is the primary goal is to reduce barriers to participation by firms not typically willing to subject themselves to the typical Government acquisition bureaucracy. In particular, the Competition in Contracting Act, Bayh-Dole & Rights in Technical Data, Truth in Negotiations Act, Contract Disputes Act, Procurement Protest System, and the Procurement Integrity Act (OUSD[AT&L], 2002) do not apply. Consequently, agencies can streamline competition and cost accounting, and agree to forgo intellectual property considerations. OTs require some level of cost sharing between Government and industry, or some other "in-kind" consideration in lieu of cost share. OTs are used much less frequently, and are much less constrained, than the FAR. For these reasons, anecdotally, procurement via OTA is typically considered "riskier" than procurement under the FAR. It is, therefore, not surprising that procurement professionals who are familiar with contracting under the FAR benefit from additional training regarding why and how OTs may be applied (Arendt et al., 2018).
- *Broad Agency Announcement:* The Broad Agency Announcement (BAA) is a competitive solicitation procedure used to obtain proposals for basic and



applied research and that part of development not related to the development of a specific system or hardware procurement. The BAA is described in FAR 6.102, Use of Competitive Procedures, and FAR 35.016, Broad Agency Announcements. The type of research solicited under a BAA attempts to increase knowledge in science and/or to advance the state of the art as compared to practical application of knowledge (“Broad Agency Announcements,” 2017).

- *Existing contractual vehicle (GSA Schedule/GWAC):* GSA Schedules are fast, easy, and effective contracting vehicles for both customers and vendors. For GSA Schedules, GSA establishes long-term Government-wide contracts with commercial companies to provide access to millions of commercial products and services at volume discount pricing (GSA, 2018). The Government can also buy cost-effective, innovative solutions for information technology (IT) requirements through Government Wide Acquisition Contracts (GWACs). GWACs provide access to IT solutions such as systems design, software engineering, information assurance, and enterprise architecture solutions (GSA, 2017a).

Source Selection/Evaluation Approach

The evaluation strategy consists of the rationale used to evaluate the performance of an I-PREDICT Offeror who is proposing to work on the project. The evaluation strategy is used to ultimately make a source-selection decision and award the offeror a contract or agreement to perform. For this project, we examined four options:

- *White paper/paper proposal:* A white paper or paper proposal is a written persuasive argument that is used to respond to a Government solicitation. White papers are defined as shorter, more tailored written responses to a Government solicitation than a traditional full paper proposal which may be anywhere from dozens of pages to hundreds of pages in length. White papers/paper proposals may be written in response to a Request for Proposal (RFP), Statement of Work (SOW), Statement of Objectives (SOO), BAA, or Request for Project Proposal (RPP).
- *Oral proposal/demonstration:* “Oral presentations (or demonstrations) by offerors as requested by the Government may substitute for, or augment, written information. Use of oral presentations as a substitute for portions of a written proposal can be effective in streamlining the source-selection process. Oral presentations may occur at any time in the acquisition process, and are subject to the same restrictions as written information, regarding timing (see FAR 15.208) and content (see FAR 15.306). Oral presentations provide an opportunity for dialogue among the parties” (FAR 15.208, 2005; FAR 15.306, 2005).
- *Challenge event:* Challenges are related to demonstrations but are issued in terms of operational needs. Challenges are accompanied by mechanisms for evaluating proposed solutions and contractual terms for provider participation. Any challenge should be transparent and understandable. It should let challengers prove that their solution is the capability sought by the Government. This forces the Government to design a challenge that, if met, proves that the offered solution provides the needed capability. Typically, solutions take the form of simplified implementations, and evaluations assess how well a solution satisfies the need in a real-world operational environment. A well-crafted challenge, accompanied by clear and effective assessment



methodologies and appropriate contracting vehicles, leads to sound and effective acquisitions (Arendt et al., 2018).

- *Combination/hybrid*: A combination or hybrid approach may be any grouping of white paper, proposal, oral proposal, demonstrations, and/or challenge event used to make I-PREDICT award decisions to vendors for integration, component models, and/or biomechanical experiments.

Incentive Approach

The incentive approach is the rationale used to motivate a potential I-PREDICT integrator, model component providers, and biomechanical experimentalists to achieve cost, schedule, and performance requirements. Incentives may be monetary or non-monetary in nature. There were six incentive options that were considered for this project:

- *Cost-plus-fixed-fee contract*: “A cost-plus-fixed-fee contract is a cost-reimbursement contract that provides for payment to the contractor of a negotiated fee that is fixed at the inception of the contract” (FAR 16.3).
- *Cost-plus-incentive-fee contract*: “The cost-plus-incentive-fee contract is a cost-reimbursement contract that provides for the initially negotiated fee to be adjusted later by a formula based on the relationship of total allowable costs to total target costs. This contract type specifies a target cost, a target fee, minimum and maximum fees, and a fee adjustment formula. After contract performance, the fee payable to the contractor is determined in accordance with the formula” (FAR 16.4).
- *Time and materials contract*: “A time-and-materials contract provides for acquiring supplies or services on the basis of: (1) Direct labor hours at specified fixed hourly rates that include wages, overhead, general and administrative expenses, and profit; and (2) Actual cost for materials (with exceptions)” (FAR, 16.6).
- *Firm Fixed Price*: “A Firm-Fixed-Price (FFP) contract provides for a price that is not subject to any adjustment on the basis of the contractor’s cost experience in performing the contract. This contract type places upon the contractor maximum risk and full responsibility for all costs and resulting profit or loss. It provides maximum incentive for the contractor to control costs and perform effectively and imposes a minimum administrative burden upon the contracting parties” (FAR 16.2).
- *Data rights*: “Within Government, the concern for intellectual property (IP) is primarily focused on the issue of ‘data rights.’ The term ‘data rights’ is a shorthand way to refer to the license rights that the Government acquires in two types of deliverables: technical data and computer software” (DoD OSA—Data Rights Team, 2014). For the I-PREDICT project, IP rights could be used as incentive for participants to deliver a successful model on time and budget. For example, the project could allow these participants to continuing using the I-PREDICT model even after the project was over for their own internal purposes. Such an arrangement would be of mutual benefit to the participants and the Government.
- *Combination/hybrid*: A combination/hybrid incentive strategy includes any grouping of cost plus fixed fee, cost plus incentive fee, time and materials, firm fixed price, and intellectual property as a part of an overall incentive package for a given contract or agreement. A combination strategy allows for the use of multiple approaches for varying tasks throughout the performance



period depending upon the performer and scope of the work being performed. The combination strategy allows the Government to take advantage of the benefits of multiple incentive approaches while mitigating their independent risks.

Intellectual Property Approach

“IP broadly refers to intangible ‘creations of the mind’—inventions, literary and artistic works, unique business names and symbols, and so forth. Owners are granted certain exclusive rights to control the use and dissemination of their intellectual properties. (“Intellectual Property,” 2017).

The IP strategy for a project is used to identify and develop a plan managing IP and related issues from the inception of the project throughout the life cycle. The key question that must be answered when developing an IP strategy is the following: What IP does the project need to maximize opportunities for competition and acquisition flexibility throughout the life cycle?

When the IP such as technical data or computer software are not available for the Government to distribute to a third party throughout the life cycle, it creates vendor lock. Vendor lock is where the Government finds itself inexorably tied to a vendor for key aspects of a project, thus giving the vendor a “monopoly” over the Government following contract award. As a result, the IP strategy must be identified and negotiated prior to contract award and evaluated during source selection. This is also a key factor when consideration is made for use of IP as part of an incentive package as described in the previous sub-section (DoD OSA—Data Rights Team, 2014). There were two IP options, the restricted/proprietary model and the open/competitive model, that were considered for the I-PREDICT project.

- *Restricted/proprietary model (DoD OSA—Data Rights Team, 2014):* When EITHER the data rights, OR the data deliverables do not allow the data to be used or released for competitive development or sustainment activities.
 - **Data Rights:** Standard License rights for technology developed 100% private expense: Limited Rights (LR), Restricted Rights (RR), or customary commercial license (CCL) for commercial computer software (CCS).
 - **Data Deliverables:** No contract requirements for delivery of necessary data or delivered data lacks technical information needed for development/sustainment or delivered with restriction.
- *Open/competitive model (DoD OSA—Data Rights Team, 2014):* When BOTH the data rights AND the data deliverables allow the data to be used or released for competitive development or sustainment activities.
 - **Data Rights:** Standard License rights for technology developed 100% Government funds or mixed funding: Unlimited Rights (UR), or Government Purpose Rights (GPR), respectively. Form, Fit, and Function (FFF) and Operation, Maintenance, Installation, and Training (OMIT) data qualify for UR regardless of funding.
 - **Data Deliverables:** Must have both a contract requirement to deliver the data, and deliverable data with the level of technical detail necessary for the desired development/sustainment activity.



Project Strategies

Upon identification and definition of the respective technical and acquisition options for the I-PREDICT project, they were combined to develop a set of project strategies for the project to consider before moving ahead. A total of three project strategies were developed to address the needs and complexity of the I-PREDICT project: Open Systems Architecture (OSA) strategy, Single model–individual performer strategy, and a single model–multiple performers strategy. Each strategy was defined and then each technical and acquisition option was assessed for its usability within that particular strategy. Strengths and weakness of the strategies were then outlined based on the usability of the technical and acquisition options and a final strategy selected. We describe each strategy below, providing strengths and weakness of each and providing justification for the chosen strategy.

Open Systems Architecture (OSA) Strategy

Definition and Overview

An Open Systems Architecture (OSA) is a technical architecture that adopts open standards supporting a modular, loosely coupled, and highly cohesive system structure. An OSA ensures that key interfaces within the system and relevant design disclosure are openly published and available for all. The key enabler for open architecture is the adoption of an open business model (OBM) that permits the collaborative innovation of numerous participants across the enterprise. The OBM permits shared risk, maximizes reuse of assets, and reduces total ownership costs. The combination of open architecture and an OBM permits the acquisition of an OSA that promise to yield modular, interoperable systems. OSA systems, by definition, allow components to be added, modified, replaced, removed, and/or supported by different vendors throughout the life cycle to afford opportunities for enhanced competition, innovation and maximize opportunities for acquisition flexibility (DoD OSA—Data Rights Team, 2013). Strengths and weaknesses of the strategy are outlined in Table 1. If this project strategy is selected, to ensure this flexibility, the project will use a solver-independent language, an open CAD anatomy to be used by all performers, and documented open standards for component interface requirements and variable component fidelity.



Table 1. Strengths and Limitations of the OSA Project Strategy

Strengths of the OSA Strategy	Limitations of the OSA Strategy
Future development of human body model components can be successfully and easily integrated into a full human body model.	This strategy risks delivering a modeling framework while under-delivering on an actual model due to focus on modeling framework.
Development of open standards for human body modeling may promote competition among model developers and drive future model development.	Development of the framework will add substantial complexity to the pre- and post-processing tools.
Solver independence will promote additional flexibility for the end users by allowing the users to leverage strengths of each solver.	A standardized language for human body modeling that results in identical simulation results across multiple solvers will require buy-in from the solver developers, which may require changes to the structure of their software.
	Limited coordination and communication between model developers and experimentalists may limit the required cooperation between these two roles.
	Potential for a lack of coordination and communication among project performers, which may impact the creation of OSA standards and may result in discrepancies in the capabilities and accuracy of model components.
	OSA strategy may prove to be difficult to execute with respect to overall contract management, as well as the associated incentive structure for performers due to the sheer number of variables the OSA strategy needs to consider.

Single Model–Individual Performer Strategy

Definitions and Overview

The single model–individual performer strategy was defined as a single performer executing or sub-contracting all the tasking related to the development of the I-PREDICT FNC. This strategy was designed to ensure the delivery of a functioning model that meets a set of pre-defined, Government-supplied requirements outlined in a statement of objectives. Strengths and weaknesses of the strategy are outlined in Table 2. If this strategy is implemented, solver selection will be made *a priori* to avoid the eventual performer delivering an I-PREDICT model that is incapable of integrating with existing DoD models or hazards, PPE, and vehicles. Freedom will be granted to the performer to use or acquire component-level models that they think are best suited for the full body model and to implement interfaces and fidelity levels they believe are most appropriate to accomplish the requirements. Anatomy can either be given to the performer by the Government or the performer would create their own anatomy. Experimental data gathered throughout the project will assist in informing these decisions. The delivery at the end of the period of performance will be a turn-key model that will be able to selectively alter fidelity, morph anatomy, and change posture as needed to accurately quantify human responses to military hazards.



Table 2. Strengths and Limitations of the Single Model–Individual Performer Project Strategy

Strengths of the single model-individual performer strategy	Limitations of the single model–individual performer strategy
Reduces Government project management burden as the Government will be only interacting with a single performer.	Selection of single performer may prioritize one aspect of the project over the other, with the effect of under-delivering on the needs of the Government stakeholder defined use cases.
Grants flexibility during the period of performance to rapidly alter fidelity levels, interfaces, pre- and post-processing tools, or other technical products.	A single performer is unlikely to be the premiere subject matter expert in development of each model component piece.
One performer streamlines deployment to the fleet.	Development of requirements to vet performers early in the project may limit performer flexibility later in the period of performance.

Single Model–Multiple Performers Strategy

Definitions and Overview

The single model–multiple performer strategy was defined as a group of performers executing explicitly defined tasking to deliver the I-PREDICT FNC. The strategy was designed to ensure some future flexibility while safeguarding against under-delivery. Strengths and weaknesses of the strategy are outlined in Table 3. If this project strategy is selected, the integrator role will be responsible for the delivery of the final model, they will be beholden to additional performers that will be delivering anatomy (a single representative human from a single performer), component level models based on project standard anatomy, and experimental results on the biomechanical response to inform the development of these models. Multiple performers will allow for the use of technical leads for different body regions that will be responsible for oversight over the model development and experimentation within that region, helping to ensure that the model is delivered with the state-of-the art technology. Technical leads will also ensure appropriate integration of experimental data gathered throughout the project into the component models and model validation. Development of interface and fidelity definitions via consultation between model component developers and the whole-body integrator will allow for model complexity where it is needed but simplicity where it is not, decreasing unnecessary computational expense.



Table 3. Strengths and Limitations of the Single Model–Multiple Performers Project Strategy

Strengths of the single model–multiple performers strategy	Limitations of the single model–individual performer strategy
Provides flexibility for rapid model updates as challenges arise while also ensuring that model component development is handled by subject matter experts.	Possibility of indecision if the performers disagree and no consensus can be reached.
Potential performers are already familiar with this leadership structure and the outlined technical options because of their exposure during the development of GHBMC human body model.	Managerial role by Government adds burden and shifts responsibility for under-delivery away from project performers and onto the Government.
Technical leads for body regions will help to ensure that the experimental data is being used to parameterize and validate a robust and accurate model.	Multiple model component providers open the possibility for component level models with varying degrees of accuracy.
The strategy allows for the development of fidelity and interface standards via the appropriate subject matter experts, granting flexibility to model developers and validation by the TC.	Government learning curve to stand up and manage a TC using this strategy.
Establishment of the TC provides the Government with an organizational structure to go back to if/when the model requires updates or maintenance	
Grants flexibility to leverage innovation from a wide range of partners from industry and academia while residing under a structure to enable efficient Government communication and collaboration with performers.	

Analysis of Alternatives

Figure 2 provides the technical option usability summary, and Figure 3 provides the acquisition options usability summary. Green highlighting indicates that an option can be used within the strategy with minimal limitations, gold highlighting indicates that an option is usable but has limitations that are considerable, and orange highlighting indicates that the limitations of the option supersede the strengths or that the option is not feasible for the strategy.

Experimental biomechanics	Government provided methods Performer developed methods Combination methods	Experimental biomechanics	Government provided methods Performer developed methods Combination methods	Experimental biomechanics	Government provided methods Performer developed methods Combination methods
Solver	Solver independence Performer solver selection Preemptive solver selection	Solver	Solver independence Performer solver selection Preemptive solver selection	Solver	Solver independence Performer solver selection Preemptive solver selection
Anatomy	Government provided CAD Performer supplied CAD	CAD Anatomy	Government provided CAD Performer supplied CAD	CAD Anatomy	Government provided CAD Performer supplied CAD
Anthropomorphic variability	Multiple CAD anatomies Morphing CAD	Anthropometry and posture	Multiple CAD anatomies Morphing CAD	Anthropometry and posture	Multiple CAD anatomies Morphing CAD
Interfaces	Interface standards Performer defined interfaces	Interfaces	Interface standards Performer defined interfaces	Interfaces	Interface standards Performer defined interfaces
Fidelity	Fidelity standards Performer defined fidelity	Fidelity	Fidelity standards Performer defined fidelity	Fidelity	Fidelity standards Performer defined fidelity
VV&A	Government V&V Developer V&V Alternate developer V&V Combination methods V&V	VV&A	Government V&V Developer V&V Alternate developer V&V Combination methods V&V	VV&A	Government V&V Developer V&V Alternate developer V&V Combination methods V&V
Pre/post processing tools	Government provided tools Performer developed tools	Pre/post processing tools	Government provided tools Performer developed tools	Pre/post processing tools	Government provided tools Performer developed tools
OSA		Single model – individual performer		Single model – multiple performers	

Figure 2. Assessment of Technical Options for I-PREDICT



Leadership Structure	Government integration	Leadership Structure	Government integration	Leadership Structure	Government integration
	Industry/academia multiple		Industry/academia multiple		Industry/academia multiple
	Industry/academia single		Industry/academia single		Industry/academia single
	Technical committee		Technical committee		Technical committee
Contracting	ID/IQ	Contracting	ID/IQ	Contracting	ID/IQ
	C Contract		C Contract		C Contract
	Other transaction authority		Other transaction authority		Other transaction authority
	BAA		BAA		BAA
	Existing vehicle		Existing vehicle		Existing vehicle
Source Selection Evaluation	White paper / paper proposal	Source Selection Evaluation	White paper / paper proposal	Source Selection Evaluation	White paper / paper proposal
	Oral proposal / demonstration		Oral proposal / demonstration		Oral proposal / demonstration
	Challenge event		Challenge event		Challenge event
	Combination		Combination		Combination
Incentive	Cost plus fixed fee	Incentive	Cost plus fixed fee	Incentive	Cost plus fixed fee
	Cost plus incentive fee		Cost plus incentive fee		Cost plus incentive fee
	Time and materials		Time and materials		Time and materials
	Firm fixed price		Firm fixed price		Firm fixed price
	IP Licenses		IP Licenses		IP Licenses
	Combination		Combination		Combination
Intellectual Property	Restricted proprietary model	Intellectual Property	Restricted proprietary model	Intellectual Property	Restricted proprietary model
	Open competitive model		Open competitive model		Open competitive model
OSA		Single model – individual performer		Single model – multiple performers	

Figure 3. Assessment of Acquisition Options for I-PREDICT

Preferred Project Strategy

Based on the evaluation of the three strategies, I-PREDICT chose the single model–multiple performer strategy. Select technical and acquisition options within the strategy are indicated in Table 4. The single model–multiple performer project strategy increases communication and collaboration among potential performers which is expected to result in a higher quality, more robust FNC. The strategy accomplishes this in two ways. The first is by leveraging the MTEC OTA acquisition vehicle, which allows for the Government and performers to interact and collaborate more frequently and freely than traditional FAR-based acquisition vehicles. The second is by establishing a TC, which the other two approaches cannot use. In this capacity, the TC meets regularly to discuss project progress and oversees the model development and experimental work for each body region. The single model–multiple performer acquisition strategy will allow the project to be agile and adaptable as the requirements are updated throughout the period of performance. Increased communication resulting from the use of both the MTEC OTA and TC will allow rapid changes to the modeling and experimental work. The OTA vehicle allows additional RPPs to be posted and awarded on reduced time scales that traditional FAR-based acquisition approaches simply cannot achieve. Use of the TC and the OTA acquisition vehicle within this strategy also provides benefits beyond the other two approaches for future updates to the model throughout the life cycle as warfighter needs and potential use cases evolve. Having the TC in place with the OTA allows for the I-PREDICT model to live on in perpetuity, granting the Navy or any future Government user the ability to quickly release RPPs under the OTA and award performers for model updates as needed.

Implementation of the Single Model–Multiple Performer Strategy

To implement the single model–multiple performer strategy, the project seeks to leverage the Medical Technology Enterprise Consortium using OTA and a three-phased execution strategy. The steps below describe how ONR created a business relationship with MTEC, how the consortium model can be used when working under an OTA, and the three-phased strategy for bringing performers on contract to stand up the project.

Table 4. Selected options for single model–multiple performer strategy

Technical options	Experimental biomechanics	Combination methods
	Solver	Preemptive solver selection
	CAD Anatomy	Performer supplied CAD
	Anthropomorphic variability	Morphing CAD
	Interfaces	Performer defined interfaces
	Fidelity	Performer defined fidelity
	VV&A	Combination methods
	Pre/post processing tools	Performer developed tools
Acquisition options	Leadership structure	Technical committee
	Contracting	Other transaction authority
	Source Selection Evaluation	Combination hybrid
	Incentive	Combination hybrid with IP incentives
	Intellectual Property	Open competitive model

Medical Technology Enterprise Consortium (MTEC)

MTEC is a collaboration between industry and academia to enable R&D, in cooperation with the U.S. Army Medical Research and Materiel Command (USAMRMC) and other Government agencies in the biomedical sciences. The purpose of MTEC is to protect, treat, and optimize the health and performance of U.S. military personnel. MTEC is a nonprofit corporation with the following principal objectives: (1) biomedical research and prototyping, (2) exploration of private sector technology opportunities, (3) technology transfer, and (4) deployment of intellectual property (IP) and follow-on production (Medical Technology Enterprise Consortium, 2018).

The scope of MTECs R&D falls into six primary scoping categories that fall within the scope of the OTs they execute. These categories include (1) Prevention, Diagnosis, and Treatment of Infectious Diseases; (2) Care of Combat Casualties; (3) Clinical and Rehabilitative Medicine; (4) Military Operational Medicine; (5) Medical Simulation and Information Sciences; and (6) Advanced Medical Technologies (Medical Technology Enterprise Consortium, 2018). In order to access the OTA and ultimately seek to leverage MTEC, ONR began a formal relationship with USAMRMC, for which ONR was required to do the following: (1) Completion of a Department of the Treasury Interagency Agreement (2700a Instructions and 2700b form); (2) Completion of an ONR Inter-Service Support Agreement (DD1144); (3) Acceptance of Department of the Navy General Terms & Conditions (GT&C); (4) Completion of an Annual Contracting/Assistance Agreement Workload Estimate for MTEC; (5) Submission of a pOTA–Project description overview for approval and acceptance by MTEC which included the following information about the project: (a) definition of the prototype to be developed and collaboration plans; (b) detailed requirements for the MTEC solicitation; (c) funding plan and any specific cost-share or private funding requested; (d) evaluation plan; criteria and plan for whitepaper/proposal evaluation; (e) project management plan with a Sponsor Office Technical Representative



(SOTR); (f) description of the end goal with the requirement with MTEC and any anticipated follow-on actions (Medical Technology Enterprise Consortium, 2018).

Consortium Model Using OTA

By gaining access to MTEC, ONR can leverage OTA in furtherance of the I-PREDICT single model–multiple performers project strategy granting access to numerous members of industry and academia to perform R&D in a highly streamlined manner relative to traditional FAR-based contracts. A consortium is defined as “an association of two or more individuals, companies, organizations, or Governments (or any combination of these entities) with the objective of participating in a common activity or pooling their resources for achieving a common goal” (Eilenberger, 2016). Consortia are open to all entities and entrance and participation is based on an entity’s approval of an application, payment of a small annual fee, and the execution of a Consortium Member Agreement. This agreement provides rules and operating procedures that govern activity within the consortium to include procedures for handling intellectual property and data rights (Eilenberger, 2016). Consortia are often established for conducting shared research and development on technologies for the consortium’s member companies, and in this case, also for the Government (Arendt et al., 2018).

The consortium model gets its statutory authority from the National Cooperative Research and Production Act (NCRPA) of 1993 (15 U.S.C. § 4301-06), which encourages innovation and collaboration between industry, academia, and the Government. The act also facilitates trade and helps to promote competition within the marketplace and is “aimed at reducing Governmental obstacles to the commercialization of new technology” (Bianco, n.d.).

The consortium model helps participants (e.g., Government, industry, and academia) to avoid duplication of effort and to be more efficient by sharing resources, information, resources, talent, and expertise. Furthermore, results of the research within the consortium are typically shared, making all members more competitive within the marketplace. It can be said that industry starts consortia for the same reasons that the Government does. John M. Eilenberger, Jr., Chief of the Contracting Office at the Army Contracting Command–New Jersey, noted some additional benefits of this consortium approach. These include that it creates relationships where they may not have otherwise occurred, allows for ease of communication, leverages capabilities, provides for clearer communication of needs and priorities, and can more easily obligate funds (Eilenberger, 2016). The Government establishes consortia for performing work within a given area of interest, technology profile, or capability gap. The Government’s relationship with a consortium is typically solidified through a business agreement using OTA with a single point of contact: the Consortium Agent, a non-profit business entity. The Consortium Agent, or prime contractor, has a direct relationship with consortium members (industry, academia, small businesses, and non-traditional suppliers), or sub-contractors, typically through a Consortium Member Agreement and makes payment to these entities through a commercial or technology initiative agreement. The Consortium Member Agreement is referenced within the OTA, but it is not part of it. The Consortium Agent works directly with the consortium members, as shown in Figure 4. Once a consortium model using OTA is established, the Government can start work. The Consortium Agent earns a small administrative fee and is paid for the work accomplished by its members. The Consortium Agent then passes the remaining funds on to the consortium entity that “wins” the work through a commercial or technology initiative agreement. It is important to note that the Government can utilize both RDT&E and Operations and Maintenance (O&M) funding, which offers flexibility in choosing the work and initiatives to be accomplished, executed, and, ultimately, funded. Using this model, the



Government can purchase prototypes, conduct intensive R&D, and even execute a sole-source follow-on procurement for additional products (Arendt et al., 2018).

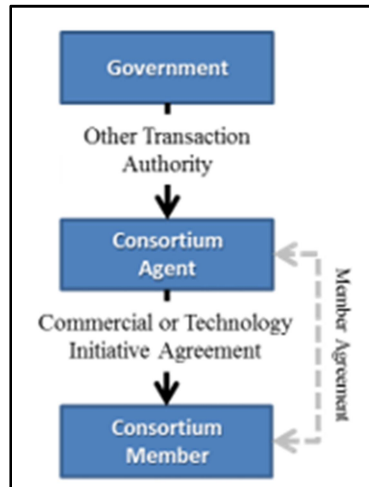


Figure 4. Government -Consortium Relationships

The method enabled by the consortium model lowers the barriers to entry for industry, non-traditional suppliers, small businesses, and academia that tend to be very innovative but may shy away from the bureaucracy of Government acquisition. This model allows the Government to tap into colleges and universities, laboratories, and small innovative companies, experts, and teams without the typical barriers put forth by federal regulations and policies that do not apply when using OTA. Furthermore, this model incentivizes innovation, collaboration, and communication, and has proven to be a win-win for both the Government and member entities of the consortium. Using this model, the Government can purchase prototypes, conduct intensive R&D, and even execute a sole-source follow-on procurement for additional product (Arendt et al., 2018).

I-PREDICT's Three-Phase Implementation Strategy

To maximize use of the OTA-Consortium model afforded to ONR via MTEC, a three-phased implementation of the single model–multiple performers implementation strategy was developed. This strategy can easily be tailored and applied for others where OTAs are being used to perform R&D and develop prototypes with highly complex technical requirements. The approach presented below allows for maximum collaboration not only between the Government and performers, but also amongst the performers so that they may work together in a highly flexible environment to deliver cutting-edge solutions to the sponsor. The three phases for this acquisition strategy begin with Phase 1, consisting of a simple white paper selection. Those offerors who receive favorable evaluations in Phase 1 are down-selected for participation in Phase 2. Phase 2 is an oral proposal/demonstration. Those proposers who receive favorable evaluations in Phase 2 are down-selected for Phase 3. Phase 3 is the use of a Technical Development Team (TDT) to collaboratively develop requirements for a statement of work. All participants then become part of the TC and thereby are eligible to submit a full proposal in response to the statement of work. Those members who are not selected as performers following full proposal evaluations would remain as participants on the TC to serve in an advisory capacity to the Government, with opportunities to bid against future work on I-PREDICT as opportunities arise. Each of these three phases of the acquisition strategy are addressed in more detail below.

Phase I Solution Brief/White Paper

Offerors for the I-PREDICT project will be required to submit a Solution Brief, which describes the overall technical concept and approach along with the viability toward achieving stated outcomes of the I-PREDICT project. The value of using the solution brief under the OTA versus a traditional paper-based proposal is the streamlined format (limited to only 10 pages) and evaluation process that can help narrow down contenders from pretenders. To complete the solution brief, offerors will be required to provide the following information:

- *Title page* that references the RPP and includes the Offeror's contact information
- *Executive summary* that provides a brief description of the methodology and technology the Offeror will employ, why it is relevant to the proposed objectives, and how the Offeror has completed similar work in the past.
- *Methodology/technology approach* that outlines the proposed methodology in sufficient detail to show a clear course of action as it relates to the topic area of interest.
- *Relevant experience* that identifies any work of a similar nature that could be used to gauge the effectiveness and worthiness of the technical or methodological approach.
- *Company viability* which provides a quick overview of the company or entity

Solution briefs will then be evaluated based upon the following four criteria and offerors will then be down-selected for participation in the Phase 2 Oral Presentations/Demonstrations:

- Feasibility of the proposed solution and its alignment with the RPP's topic area;
- Relevancy of the proposed methodology/technology/solution to the topic area with special interest toward any innovation or previously underutilized capabilities;
- Strength of the organization/team proposed to complete the work and its financial stability to potentially continue the maturation of the system beyond the scope of the I-PREDICT RPP; and
- Inclusion of nontraditional or small business participation or a 1/3 cost share.

Phase II Oral Presentations/Demonstrations

In Phase 2, it is envisioned that the Offeror(s) will provide a "pitch" of the proposed project during an in-person meeting with ONR. The pitch is intended to provide more details about the viability of the proposed work outlined in Phase 1. Offerors who are invited to give a Solution Brief Pitch are provided with the specific areas of interest to be included in the pitch at the end of Step 1 during the time of invitation to advance into Step 2. Offeror(s) will be asked the following information in their pitch:

- *Description*: The Offeror will provide a more robust description of their approach.
- *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.
- *Prototype:* A description of how this work effort will facilitate the development of the I-PREDICT prototype must be described.
- *Data rights assertions:* The Solution Brief will identify 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.

Phase III Technical Development Team/Technical Committee Selection

It is envisioned that those offerors who are down-selected to participate in the TDT are referred to as finalists. These finalists are invited to attend a TDT meeting in person to help the Government scope out the technical requirements for the program in more detail to ensure that the project is organized to achieve its goals within the designated period of performance. These technical requirements will be worked into a Request for Project Proposals (RPP). Only members of the TDT will be invited to respond to the RPP. Finalists who are members of the TDT will be provided a participation stipend for their support in the TDT. The RPP to which the TDT members will respond includes the following components for evaluation:

- *Statement of work:* The Offeror is required to provide a detailed SOW. Based on the results of the Technical Evaluation, the Government reserves the right to negotiate and revise any or all parts of the SOW. Offerors will have the opportunity to concur with revised SOW and revise cost proposals as necessary.
- *Cost proposal submission:* Section I: Cost Proposal Narrative required. Separately, Section II: Cost Proposal is required.
- *Warranties and Representations:* If Nontraditional Defense Contractor participation is proposed, Warranties and Representations are required.
- *Royalty Payment Agreement or Additional Research Project Award Assessment:* Each Offeror is required to select either the MTEC Additional Assessment Fee or the Royalty Agreement (available on the MTEC members only website), not both, and submit a signed copy with the proposal.

It is envisioned that if a member of the TDT is not selected for funding, ONR may extend an invitation for them to become members of the TC. The advancement of non-awardee members of the TDT to become members of the TC is only by invitation. Invitations for non-awardees to participate on the TC may be renewed or rescinded on an annual basis at the discretion of ONR. Members of the TC who are Awardees will be provided funding commensurate with their final negotiated statement of work and accepted cost proposal. Members of the TC who are not Performers but who have been invited for TC participation only will receive an annual TC participation stipend.



Program Execution

The TC will operate with eight distinct roles for executing the program, some held by the Government, one with an FFRDC (MITRE), and several with industry/academia performers. The TC will be responsible for overseeing and executing the work performed under the program. In cases where there are new technical requirements, the TC may then again jointly prepare a SOW and offer it for proposals to the TC members. Once the TC is initially formed, all members will be asked to execute their roles based on and outlined in Figure 5 and the following descriptions:

- **Office of Naval Research Program Officer:** ONR is the funding agency managing the program. The ONR Program Officer will have ultimate decision authority for program goals, communication paths, responsibilities, program activities and scope, and delivery from all participants. The ONR Program Officer is supported by in-house staff and contractors.

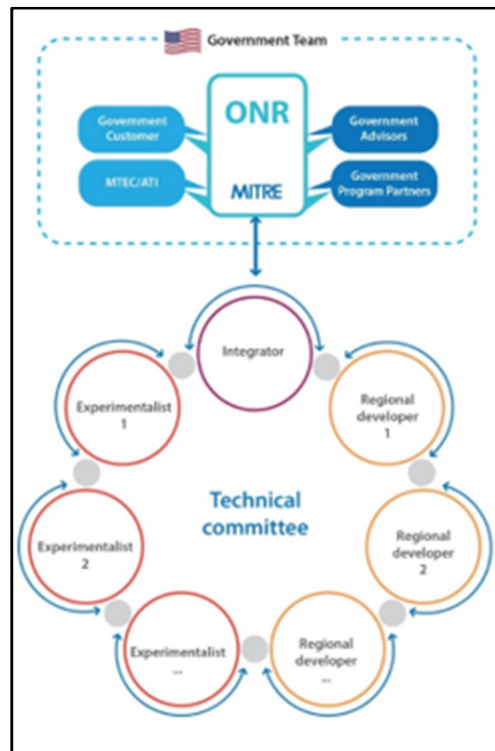


Figure 5. Technical Committee Structure

- **Government Program Partners:** One or more Government personnel from programs of record in the Navy or other service may be asked to provide direct program support including technical advice, use case development for program products, outreach to communities of interest (e.g., operational, medical, materiel, test and evaluation), interagency integration, advocacy, technology transition, and/or technology readiness assessments among potentially other program functions. Program support may include direct participation in internal ONR program meetings at the request of ONR. Government Program Partners may be consulted for their opinions on internal ONR program decisions. Government Program Partners will have no program decision authority.

- **Government Customers:** Internal funding for FNCs at ONR require one or more DoD organizations (hereafter, “Government Customers”) to become signatories to a Technology Transition Agreement (TTA), so that FNC investments are measurably relevant to TTA signatory organization mission objectives. Government Customers provide vital information about their organization’s mission objectives in the form of use cases for how I-PREDICT Program technologies might fulfill their organization’s missions. Government Customers will have no program decision authority. Government Customers retain control of their funding, and TTA signatory authority. Government Customers will have a substantial influence over program priorities and execution.
- **Government Advisors:** One or more Government personnel from programs of record in the Navy or other service may provide advice to ONR on their organization’s mission objectives and/or technical matters relevant to the I-PREDICT Program. Government Advisors will have no program decision authority.
- **MITRE:** As a DoD trusted agent, The MITRE Corporation will inform and advise ONR on technical matters and to mitigate programmatic and technical risk, to serve as a hub for communication among participants and stakeholders to develop technology acquisition strategies, and other activities as required by the Government. MITRE will have no program decision authority, except as delegated by the ONR Program Officer.
- **Government Team:** The “Government Team” is expected to consist of ONR, Government Program Partners, Government Customers, Government Advisors, and The MITRE Corporation as detailed above. This Team will form the nexus of decision making for the Government on all matters for program performance and delivery of technical products, in consultation with TC members and funded performers as detailed below. Ultimate decision authority rests with ONR.
- **Program performers and Technical Committee Members:** During various phases of the I-PREDICT project, funded performers from academia, industry, and/or Government may serve as performers and/or TDT members during the formulation of the funding vehicle and its goals. Once funded as performers and/or otherwise invited to serve as TC members, they will be expected to offer technical advice on program goals and scope, and to respond to ONR and the Government Team as described above. TC members will have no program decision authority.
- **Medical Technology Enterprise Consortium (MTEC)/Advanced Technology International (ATI):** In its capacity as Consortium Manager for MTEC, ATI will act as an administrative liaison between the ONR Program Officer/MITRE and offerors, TDT members, and TC members. In this role, ATI will publish ONR Program Officer–approved documentation related to I-PREDICT; communicate messages or sharing of information to offerors, TDT members, and TC members on behalf of the FFRDC and ONR; collect, organize, and share formal solicitation responses and inquiries from I-PREDICT participants with the ONR Program Officer; provide management and administration of funds dispersal to program performers upon approval from ONR; and provide management and administration of the base MTEC member agreement and



individual project performer agreements with input provided by ONR and MITRE where appropriate.

Conclusion

Accurate prediction of injuries and the resulting functional incapacitation under varying military hazard conditions would provide the ability to design safe equipment and behavioral practices, and to allow commanders to weigh operational risks during the planning and execution of missions and to allocate resources appropriate to those risks. The sooner these types of highly complex, innovative technologies can be transitioned to the field, the sooner warfighters can reap the benefits of this kind of cutting-edge research. However, designing a program to deliver a computational model that provides these capabilities is fraught with technical complexity, making the acquisition of such a model challenging. This paper provides a description of a decision framework that was developed for evaluating technical and acquisition options to meet project needs, building and evaluating potential project strategies, and the process for execution of the selected strategy. Additionally, this paper outlines the use of the OTA acquisition vehicle and MTEC along with a three-phase implementation strategy for award selection to MTEC members.

It is expected that the decision framework and implementation strategy developed may be used Navy-wide or across other military Services for any R&D program that requires acquisition flexibility coupled with highly collaborative technology development. The TC aspect of this process allows a way ahead to ensure that continued improvements and upgrades of the chosen solution can be transitioned to the fleet throughout the life cycle. Ultimately, the decision framework presented herein and its supporting processes may allow programs to benefit from a unique partnership with performers, while streamlining deployment and fielding, consequently yielding safer PPE, vehicles, weapons, and training regimens for the warfighter.

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