Solicitation Number: MTEC-20-09-COVID-19_Treatment_MIDRP
“Development of Treatments for COVID-19”

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

Request Issue Date: March 25, 2020
Amendment No. 01 Issue Date: March 31, 2020

Enhanced White Paper Due Date: April 8, 2020
Noon Eastern Time Zone

Amendment No. 01 does the following:

1. Revises RPP Section 2.7
3. Incorporates BIDs Instructions

No other changes have been made.
2.7. Inclusion of Nontraditional Defense Contractors or Nonprofit Research Institutions

Enhanced White Papers that fail to meet the mandatory statutory conditions with regard to the appropriate use of Other Transaction authority, as listed below, will not be evaluated and will determined ineligible for award. Please see the MTEC PPG and Appendix 5.3 of the Enhanced White Paper Template for additional details.

Mandatory statutory conditions (the Offeror shall assert that at least one of the one of the following conditions is met):

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

(2) All significant participants in the transaction other than the Federal Government are small businesses (including small businesses participating in a program described under section 9 of the Small Business Act (15 U.S.C. 638)) or nontraditional defense contractors.

(3) At least one third of the total cost of the prototype project is to be paid out of funds provided by sources other than the Federal Government.

The Offeror 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, small business or nonprofit research institution. The nontraditional defense contractor can be an individual so long as he/she has a DUNS Number and meets the requirements in the Warranties and Representations. The significance of the nontraditional defense contractor’s, small business’ or nonprofit research institution’s participation shall 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 extent includes:

1. Supplying a new key technology, product or process
2. Supplying a novel application or approach to an existing technology, product or process
3. Providing a material increase in the performance, efficiency, quality or versatility of a key technology, product or process
4. Accomplishing a significant amount of the prototype project
5. Causing a material reduction in the cost or schedule of the prototype project
6. Provide for a material increase in performance of the prototype project
10 Enhanced White Paper Template

Page Limitation: The Enhanced White Paper is limited to thirteen (13) pages (including cover page). The following Appendices are excluded from the page limitation: (4.1) Statement of Work, (4.2) Data Rights, and (4.3) Warranties and Representations

Required Format: 12 point font (or larger), single-spaced, single-sided, 8.5 inches x 11 inches). Smaller type may be used in figures and tables, but must be clearly legible. Margins on all sides (top, bottom, left, and right) should be at least 0.5 inch.

Please note a full Cost Proposal will be requested if the Enhanced White Paper is selected for funding.
Cover Page

[Name of Offeror]
[Address of Offeror]
[Phone Number and Email Address of Offeror]

DUNS #: [DUNS #]
CAGE code: [CAGE code]

>Title of Enhanced White Paper

[Specific Requirement addressed in Enhanced White Paper]

[Offeror] certifies that, if selected for award, the Offeror will abide by the terms and conditions of the MTEC Base Agreement.

[Offeror] certifies that this Enhanced White Paper is valid for 3 years from the close of the applicable RPP, unless otherwise stated.

[A proprietary data disclosure statement if proprietary data is included. Sample:
This Enhanced White Paper includes data that shall not be disclosed outside the MTEC Consortium Management Firm and the Government and shall not be duplicated, used, or disclosed, in whole or in part, for any purpose other than to evaluate this Enhanced White Paper and negotiate any subsequent award. If, however, an agreement is awarded as a result of, or in connection with, the submission of this data, the MTEC Consortium Management Firm and the Government shall have the right to duplicate, use, or disclose these data to the extent provided in the resulting agreement. This restriction does not limit the MTEC Consortium Management Firm and the Government's right to use the information contained in these data if they are obtained from another source without restriction. The data subject to this restriction is (clearly identify) and contained on pages (insert page numbers).]
[Title of Enhanced White Paper]

SECTION 1: INITIAL SCREENING SUMMARY (2 page limit)

- Programmatic Relevance: [Provide a description of how the proposed technology needs described in this RPP.]
- TRL at time of submission: [Insert]
- Expected TRL at end of base PoP: [Insert]
- Technical Abstract: [Briefly describe project goals, hypothesis, study design, and deliverables.]
- Timeliness: [Indicate estimated time that product will be able to be deployed to the field].
- Non-Clinical Data: [Briefly describe the non-clinical data (in vitro, tox, pre-clinical data, etc.) suggesting safety and/or efficacy of the proposed therapeutic]
- Manufacturing Feasibility: [Indicate if you have demonstrated manufacturing feasibility of the candidate therapeutic. If so, briefly describe.]

SECTION 2: TECHNICAL

Section 2.1: Programmatic Relevance
- Provide the background and the Offeror’s understanding of the problem and/or technology gap/process deficiency.
- Provide a description of how the proposed technology meets the needs specified in this RPP.
- Proposed candidate therapeutic can be administered in a non-hospital environment: [Yes/No]
- Timeliness:
- Describe how quickly you will transition your technology to evaluation in humans.
- Describe how you will deploy your technology for field use.

Section 2.2: Scope Statement
- Define the scope of the effort and clearly state the objectives of the project.
- Explain if the effort is a complete solution to the requirement, or some portion thereof.

Section 2.3: Scientific Rationale / Preliminary Data
- Describe the scientific rationale for the project, including a brief description of the previous studies or preliminary data that support the feasibility of proposed work.
- Describe the non-clinical data (in vitro, tox, pre-clinical data, etc.) suggesting safety and/or efficacy of the proposed therapeutic
- Describe your demonstration of the manufacturing feasibility of the candidate therapeutic.
Section 2.4: Technical Approach

- Describe the experimental design, methods, and materials required to accomplish the proposed approach. Describe the proposed methodology in sufficient detail to show a clear course of action.
- Clinical Trials (if applicable): Clinical trials should be described in adequate detail to assess conformance with FDA regulations, guidance, and the requirements related to its appropriate pathway for development and testing.
  - Provide a description of the purpose and objectives of the study.
  - Describe the clinical intervention, medical drug, biologic, device or human exposure model to be tested. Document the availability and accessibility of the drug/compound, device, or other materials needed for the proposed research.
  - Include a description of study variables, appropriate controls and the endpoints to be tested.
  - Outline the proposed methodology (e.g., study design, data analysis, etc.) in sufficient detail to show a clear course of action. Describe potential challenges and alternative strategies where appropriate.
  - Describe current status of interactions with the U.S. Food and Drug Administration and your plan to meet all regulatory sponsor responsibilities.

Section 2.5: Anticipated Outcomes

- Provide a description of the anticipated outcomes from the proposed work. List milestones and deliverables from the proposed work.

Section 2.6: Team

- Describe the qualifications and expertise of the key personnel and organizations that will perform the proposed work.
- Indicate which organizations or types of organizations you will need to team/partner with as your technology advances into clinical evaluation and/or field use.

Section 2.7: Project Management Plan

- Describe the overall project management plan.

Section 2.8: Regulatory and Commercialization Plan

- Briefly describe the regulatory plan, including FDA pathway and designation, strategy for obtaining FDA approvals or clearances.
- Briefly describe the transition and commercialization plan, including a description of the market (civilian and military) and sustainability.

Section 2.9: Resources
• Identify any key facilities, equipment and other resources proposed for the effort. Identified facilities, equipment and resources should be available and relevant for the technical solution being proposed.

Section 2.10: Schedule
• Period of Performance: Indicate the proposed period of performance in months from award.
• Proposed Schedule: Provide a schedule (e.g. Gantt chart) that clearly shows the plans to perform the program tasks in an orderly, timely manner. Provide each major task as a separate line.

Section 2.11: Risk Identification and Mitigation
• Identify key technical, schedule, and cost risks. Discuss the potential impact of the risks, as well as potential mitigations.

SECTION 3: COST ESTIMATE

Section 3.1: Estimate Summary
• The Offeror must provide an estimate based on the technical approach proposed in the Enhanced White Paper. The following chart (tailored as appropriate) shall be included in the Enhanced White Paper. If selected for award, a full cost proposal will be requested.

<table>
<thead>
<tr>
<th>Year</th>
<th>Estimate</th>
<th>Cost Share Estimate (if applicable)</th>
<th>Total Estimate (w/ Cost Share)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Year 1</td>
<td>$</td>
<td>$</td>
<td>$</td>
</tr>
<tr>
<td>Year 2 (if applicable)</td>
<td>$</td>
<td>$</td>
<td>$</td>
</tr>
<tr>
<td>Year 3 (if applicable)</td>
<td>$</td>
<td>$</td>
<td>$</td>
</tr>
<tr>
<td>TOTAL</td>
<td>$</td>
<td>$</td>
<td>$</td>
</tr>
</tbody>
</table>

Section 3.2: Estimate Rationale
• The Offeror must provide a brief rationale describing how the estimate was calculated and is appropriate for the proposed scope or approach.

SECTION 4: APPENDICES (excluded from the page limit)

Appendix 4.1: Statement of Work
• Provide a draft Statement of Work as a separate Word document to outline the proposed technical solution and demonstrate how the contractor proposes to meet the Government objectives. Submitted information is subject to change through negotiation if the Government selects the Enhanced White Paper for award. The format of the proposed Statement of Work shall be completed in accordance with the template provided below.
The Government reserves the right to negotiate and revise any or all parts of SOW/Milestone Payment Schedule. Offerors will have the opportunity to concur with revised SOW/Milestone Payment Schedule as necessary.

Appendix 4.2: Data Rights Assertions

- 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 you should discuss any restricted data rights associated with any proposed deliverables. If applicable, complete the below table for any items to be furnished to the Government with restrictions. An example is provided.

Appendix 4.3: Warranties and Representations:

- Warranties and Representations are required. One Word (.docx or .doc) or PDF file that contains all Warranties and Representations is required.

SECTION 5: APPENDIX TEMPLATES

Appendix 5.1: Statement of Work

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

**Proposal Number:**

**Organization:**

**Title:**

**ACURO and/or HRPO approval needed:**

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

**Scope/Project Objective** *(To be provided initially by the Offeror at the time of proposal submission. Submitted information is subject to change through negotiation if the Government selects the proposal for funding.)*
This section includes a statement of what the project covers. This should include the technology area to be investigated, the objectives/goals, and major milestones for the effort.

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

State the technology objective in the first paragraph and follow with delineated tasks required to meet the overall project goals. The work effort should be segregated into major phases, then tasks and identified in separately numbered paragraphs (similar to the numbered breakdown of these paragraphs). Early phases in which the performance definition is known shall be detailed by subtask with defined work to be performed. Planned incrementally funded phases will require broader, more flexible tasks that are priced up front, and adjusted as required during execution and/or requested by the Government to obtain a technical solution. Tasks will need to track with established adjustable cost or fixed price milestones for payment schedule. Each major task included in the SOW should be priced separately in the cost proposal. Subtasks need not be priced separately in the cost proposal.

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

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

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

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

The milestones and associated deliverables proposed should, in general:

- be commensurate in number to the size and duration of the project (i.e., a $5M multi-year project may have 20, while a $700K shorter term project may have only 6);
- not be structured such that multiple deliverables that might be submitted separately are included under a single milestone;
- be of sufficient monetary value to warrant generation of a deliverable and any associated invoices;
- include at a minimum Quarterly Reports which include both Technical Status and Business Status Reports (due the 25th of Apr, Jul, Oct, Jan), Annual Technical Report, Final Technical Report, and Final Business Status Report. Reports shall have no funding associated with them.

### MTEC Milestone Payment Schedule Example

<table>
<thead>
<tr>
<th>MTEC Milestone Number</th>
<th>Task Number</th>
<th>Significant Event/ Accomplishments</th>
<th>Due Date</th>
<th>Government Funds</th>
<th>Cost Share</th>
<th>Total Funding</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>N/A</td>
<td>Project Kickoff</td>
<td>12/1/2019</td>
<td>$20,000</td>
<td></td>
<td>$20,000</td>
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<tr>
<td>2</td>
<td>N/A</td>
<td>Quarterly Report 1 (October - December, Technical and Business Reports)</td>
<td>1/25/2020</td>
<td>$ -</td>
<td></td>
<td>$ -</td>
</tr>
<tr>
<td>3</td>
<td>1</td>
<td>Protocol Synopsis</td>
<td>2/28/2020</td>
<td>$21,075</td>
<td></td>
<td>$21,075</td>
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<tr>
<td>4</td>
<td>2</td>
<td>Submission for HRPO Approval</td>
<td>2/28/2020</td>
<td>$21,075</td>
<td></td>
<td>$21,075</td>
</tr>
<tr>
<td>5</td>
<td>3</td>
<td>Submission of Investigational New Drug application to the US FDA</td>
<td>4/30/2020</td>
<td>$210,757</td>
<td>$187,457</td>
<td>$398,214</td>
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<td>6</td>
<td>N/A</td>
<td>Quarterly Reports 2 (January - March, Technical and Business Reports)</td>
<td>4/25/2020</td>
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<td>$ -</td>
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<td>7</td>
<td>N/A</td>
<td>Quarterly Report 3 (April - June, Technical and Business Reports)</td>
<td>7/25/2020</td>
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<td></td>
<td>$ -</td>
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<tr>
<td>8</td>
<td>4</td>
<td>Toxicity Studies</td>
<td>10/1/2020</td>
<td>$63,227</td>
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<td>$63,227</td>
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<tr>
<td>9</td>
<td>N/A</td>
<td>Annual Report 1</td>
<td>10/25/2020</td>
<td>$ -</td>
<td></td>
<td>$ -</td>
</tr>
<tr>
<td>10</td>
<td>5</td>
<td>FDA authorization trial</td>
<td>11/30/2020</td>
<td>$84,303</td>
<td></td>
<td>$84,303</td>
</tr>
<tr>
<td>11</td>
<td>6</td>
<td>Research staff trained</td>
<td>11/30/2020</td>
<td>$ -</td>
<td></td>
<td>$ -</td>
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<tr>
<td>12</td>
<td>7</td>
<td>Data Management system completed</td>
<td>11/30/2020</td>
<td>$ -</td>
<td></td>
<td>$ -</td>
</tr>
<tr>
<td></td>
<td></td>
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<td></td>
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<td>---</td>
<td>---</td>
<td></td>
<td></td>
</tr>
<tr>
<td>13</td>
<td>8</td>
<td>1\textsuperscript{st} subject screened, randomized and enrolled in study</td>
<td>1/1/2021</td>
<td>$150,000</td>
<td>$187,457</td>
<td>$337,457</td>
</tr>
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<td>14</td>
<td>N/A</td>
<td>Quarterly Report 4 (October - December, Technical and Business Reports)</td>
<td>1/25/2021</td>
<td>$ -</td>
<td>$ -</td>
<td>$ -</td>
</tr>
<tr>
<td>15</td>
<td>9</td>
<td>Completion of dip molding apparatus</td>
<td>3/1/2021</td>
<td>$157,829</td>
<td>$187,457</td>
<td>$345,286</td>
</tr>
<tr>
<td>16</td>
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<td>Quarterly Reports 5 (January - March, Technical and Business Reports)</td>
<td>4/25/2021</td>
<td>$ -</td>
<td>$ -</td>
<td>$ -</td>
</tr>
<tr>
<td>17</td>
<td>10</td>
<td>Assess potential toxicology</td>
<td>6/1/2021</td>
<td>$157,829</td>
<td>$157,829</td>
<td>$157,829</td>
</tr>
<tr>
<td>18</td>
<td>N/A</td>
<td>Quarterly Report 6 (April - June, Technical and Business Reports)</td>
<td>7/25/2021</td>
<td>$ -</td>
<td>$ -</td>
<td>$ -</td>
</tr>
<tr>
<td>19</td>
<td>11</td>
<td>Complete 50% patient enrollment</td>
<td>10/1/2021</td>
<td>$350,000</td>
<td>$187,457</td>
<td>$537,457</td>
</tr>
<tr>
<td>20</td>
<td>N/A</td>
<td>Annual Report 1</td>
<td>10/25/2021</td>
<td>$ -</td>
<td>$ -</td>
<td>$ -</td>
</tr>
<tr>
<td>21</td>
<td>N/A</td>
<td>Quarterly Report 7 (October - December, Technical and Business Reports)</td>
<td>1/25/2022</td>
<td>$ -</td>
<td>$ -</td>
<td>$ -</td>
</tr>
<tr>
<td>23</td>
<td>N/A</td>
<td>Quarterly Reports 8 (January - March, Technical and Business Reports)</td>
<td>4/25/2022</td>
<td>$ -</td>
<td>$ -</td>
<td>$ -</td>
</tr>
<tr>
<td>24</td>
<td>N/A</td>
<td>Quarterly Report 9 (April - June, Technical and Business Reports)</td>
<td>7/25/2022</td>
<td>$ -</td>
<td>$ -</td>
<td>$ -</td>
</tr>
<tr>
<td>25</td>
<td>13</td>
<td>Complete 100% patient enrollment</td>
<td>8/1/2022</td>
<td>$315,658</td>
<td>$187,457</td>
<td>$503,115</td>
</tr>
<tr>
<td>26</td>
<td>N/A</td>
<td>Annual Report 1</td>
<td>10/25/2022</td>
<td>$ -</td>
<td>$ -</td>
<td>$ -</td>
</tr>
<tr>
<td>27</td>
<td>14</td>
<td>Report results from data analysis</td>
<td>11/1/2022</td>
<td>$157,829</td>
<td>$157,829</td>
<td>$157,829</td>
</tr>
</tbody>
</table>
Please Note:

1. Firm Fixed Price Contracts – Milestone must be complete before invoicing for fixed priced contracts.
2. Cost Reimbursable Contracts – You may invoice for costs incurred against a milestone. Invoicing should be monthly.
3. Cannot receive payment for a report (i.e. Quarterly, Annual and Final Reports should not have an assigned Government Funded or Cost Share amount.)
4. Quarterly and Annual Reports include BOTH Technical and Business Reports (separate).
5. Final Report due date must be prior to POP end noted in subcontract.
6. MTEC Milestone Numbers are used for administrative purposes and should be sequential.
7. Task Numbers are used to reference the statement of work if they are different from the MTEC Milestone Number.

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

The shipping address is:

Classified Shipments:
- Outer Packaging
- Inner Packaging

Reporting

<table>
<thead>
<tr>
<th>Report Months</th>
<th>Due Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>January – March</td>
<td>25 April</td>
</tr>
<tr>
<td>April - June</td>
<td>25 July</td>
</tr>
<tr>
<td>July - September</td>
<td>25 October</td>
</tr>
<tr>
<td>October - December</td>
<td>25 January</td>
</tr>
</tbody>
</table>

Quarterly Reports – The MTEC research project awardee shall prepare a Quarterly Report which will include a Technical Status Report and a Business Status Report in accordance with the terms and conditions of the Base Agreement. (Required)

Annual Technical Report – The project awardee shall prepare an Annual Technical Report for projects whose periods of performances are greater than one year in accordance with the terms and conditions of the Base Agreement. (Required)

Final Technical Report – At the completion of the Research Project Award, the awardee will submit a Final Technical Report, which will provide a comprehensive, cumulative, and
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Number W81XWH-15-9-0001

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

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

Appendix 5.2: Data Rights Assertions

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.
Please indicate your assertion:
☐ Unlimited Data Rights.
☐ Government Purpose Data Rights.
☐ Restricted Government Rights as described below.

<table>
<thead>
<tr>
<th>Technical Data or Computer Software to be Furnished with Restrictions</th>
<th>Basis for Assertion</th>
<th>Asserted Rights Category</th>
<th>Name of Organization Asserting Restrictions</th>
<th>Milestone # Affected</th>
</tr>
</thead>
<tbody>
<tr>
<td>Software XYZ</td>
<td>Previously developed software funded exclusively at private expense</td>
<td>Restricted</td>
<td>Organization XYZ</td>
<td>Milestones 1, 3, and 6</td>
</tr>
<tr>
<td>Technical Data Description</td>
<td>Previously developed exclusively at private expense</td>
<td>Limited</td>
<td>Organization XYZ</td>
<td>Milestone 2</td>
</tr>
</tbody>
</table>
Appendix 5.3: Warranties and Representations:
Authority to use Other Transaction Agreement

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

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

(B) All significant participants in the transaction other than the Federal Government are small businesses (including small businesses participating in a program described under section 9 of the Small Business Act (15 U.S.C. 638)) or nontraditional defense contractors.

(C) At least one third of the total cost of the prototype project is to be paid out of funds provided by sources other than the Federal Government.

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

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

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

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

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>8. Legal Name:</td>
<td></td>
</tr>
<tr>
<td>9. DUNS #:</td>
<td></td>
</tr>
<tr>
<td>10. Dollar Value to be Awarded to Subcontractor:</td>
<td></td>
</tr>
</tbody>
</table>
11. **Point of Contact:**
   (Name, Title, Phone #, Email) | 12. **Task/Phase:**

13. **Subcontractor/Vendor is a nontraditional (Y/N)?**
14. **Subcontractor/Vendor is a nonprofit research institution (Y/N)?**
15. **Subcontractor/Vendor is a small business (Y/N)?**

16. **Significant Contribution:**
   - A - The significant contribution involves developing, demonstrating or providing a key technology. *Please describe what the key technology is; why it is key to the medical technology community, and what makes it key.*
   - B - The significant contribution involves developing, demonstrating or providing a new technology that is not readily available. *Please describe what the new part or material is and why it is not readily available.*
   - C - The significant contribution involves use of skilled personnel (such as modeling & simulation experience, medical technology design experience, etc.), facilities and/or equipment that are within the capabilities of the designated nontraditional and required to successfully complete the program. *Please describe the personnel, facilities and/or equipment involved in the proposed program and why they are required to successfully complete the program.*
   - D - The use of this designated subcontractor/vendor will cause a material reduction in the cost or schedule. *Please describe the specific cost or schedule impact to be realized.*
   - E - The use of this designated subcontractor/vendor will increase medical technology performance. *Please describe what the performance increase will be attained by the use of this designated nontraditional defense contractor.*

1 In addition to the above please provide the following information:

<table>
<thead>
<tr>
<th>Q1</th>
<th>What additional capability beyond those described in A through E above does this subcontractor/vendor have that is necessary for this specific effort?</th>
</tr>
</thead>
<tbody>
<tr>
<td>A1</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Q2</th>
<th>In which task/phase(s) of the effort will the subcontractor/vendor be used?</th>
</tr>
</thead>
<tbody>
<tr>
<td>A2</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Q3</th>
<th>What is the total estimated cost associated with the subcontractor/vendor included in the proposal? <em>Note: While cost is an indicator for the level of nontraditional defense contractor participation, there is no particular cost threshold required.</em></th>
</tr>
</thead>
<tbody>
<tr>
<td>A3</td>
<td></td>
</tr>
</tbody>
</table>
C. Signature

______________________________          ______________
Signature of authorized representative of proposing Prime Contractor  Date
**Warranties and Representations Instructions**

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

Section B must be completed if the Prime Contractor is traditional and has proposed nontraditional defense contractors, nonprofit research institutions, or small businesses. Copy, paste, and complete the table found in Section B for each participating nontraditional defense contractor, nonprofit research institutions, or small business.
8. Insert subcontractor/vendor’s legal name.
9. Insert subcontractor/vendor’s DUNS #.
10. Insert the dollar value (cost and fee) to be awarded to the subcontractor/vendor.
11. Insert the Point of Contact (Name, Title, Phone #, Email) for the subcontractor/vendor.
12. Indicate in which specific task/phase(s) of the effort will the subcontractor/vendor be used.
13. Indicate Yes (Y) or No (N) if the subcontractor/vendor is a nontraditional defense contractor (Note: A nontraditional defense contractor means an entity that is not currently performing and has not performed, for at least the one-year period preceding the issue date of the solicitation, any contract or subcontract for the Department of Defense that is subject to full coverage under the cost accounting standards prescribed pursuant to Section 1502 of Title 41 and the regulations implementing such section.).
14. Indicate Yes (Y) or No (N) if the subcontractor/vendor is a nonprofit research institution.
15. Indicate Yes (Y) or No (N) if the subcontractor/vendor is a small business (including small businesses participating in a program described under section 9 of the Small Business Act (15 U.S.C. 638)).
16. Explain the subcontractor/vendor’s Significant Contribution to the project by answering the questions below.
A - The significant contribution involves developing, demonstrating or providing a key technology. Please describe what the key technology is; why it is key to the medical technology community, and what makes it key.

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

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

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

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

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

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

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

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

General Guidance
- Nontraditional defense contractors can be at the prime level, team members, subcontractors, lower tier vendors, or "intra-company" business units, provided that the business unit makes a significant contribution to the prototype project.
- All nontraditional defense contractors must have a DUNS number.
- A foreign business can be considered a nontraditional if it has a DUNS number and can comply with the terms and conditions of the MTEC Base Agreement.
11 BIDS Instructions

THIS PAGE IS INTENTIONALLY LEFT BLANK. PLEASE SEE PRESENTATIONS BELOW.
MTEC BIDS REGISTRATION

MTEC BIDS URL:
HTTPS://ATI2.ACQCENTER.COM
BIDS New Registration

Navigate to the MTEC BIDS website and select “New Registration” from the home screen.
Select “Submitter”. 

Please select the type of account you are registering for:

Government
- Government Requirement Submitter/Evaluator/AOR – Select this in order to submit requirements, evaluate whitepapers and proposals, and/or make an award. Please note you must be approved before you will be able to access the system.

Industry
- Submitter – Select this in order to submit responses to solicitations.

SECURITY NOTICE: Unauthorized attempts to deny service, upload information, change information, or attempt to access a non-public site from this service are strictly prohibited and may be punishable under Title 18 of the U.S. Code to include the Computer Fraud and Abuse Act of 1986 and the National Information Infrastructure Protection Act.
Complete the registration form. Be sure to select how you want to receive the dual factor verification code (SMS text message is recommended).

Select “Submit Registration” to complete BIDS registration.
BIDS registration is instantaneous. It does not require any verification by the MTEC team. After successfully registering, you can submit proposals to any open MTEC RPP.

- MTEC Membership will be verified once a proposal is received and after the proposal deadline.
- Updates to submitted documents can be made anytime prior to the due date and time.
- MTEC RPP links will be opened, within BIDS, at least two weeks prior to the submission deadline.

Please note: For RPPs that are two stages (i.e. White Paper to Full Proposal) only the account that submitted the stage 1 proposal (the White Paper) will be allowed to submit for stage 2 (the Full Proposal), if selected.

**ALL PROPOSALS MUST BE SUBMITTED BEFORE THE SUBMISSION DUE DATE AND TIME. LATE PROPOSALS CAN NOT BE ACCEPTED.**
MTEC BIDS PROPOSAL SUBMISSION

MTEC BIDS URL:
HTTPS://ATI2.ACQCENTER.COM
Navigate to the MTEC BIDS site and login. After login select the “MTEC BIDS Home” link.

Login to your BIDS Account.

Then select the “MTEC BIDS Home” link.
Select the “Respond to RPP” link under the submitter tools.

Once logged in, your username will appear here.

Click the link to respond to an RPP.

RPP information is provided in this section. This includes status updates.
Select which RPP you will be responding to.

Select which RPP to respond to. If multiple RPPs are open, they will be listed here.
Complete the submission form.

- Select the technical area your submitting to as identified in the RPP.

- Shows remaining time before submission close.

***PLEASE NOTE: Your web session will expire automatically if you are idle for more than 60 minutes.***
Complete the submission form by uploading the required documents and click submit.

Once the submission form is completed select submit.
Once you have successfully submitted a proposal, you will receive a notification with your submission number (ex. MTEC-23-24-Everest-045).

- Submission documents can be modified anytime prior to the due date and time from your BIDS account.
- To make changes to your submission, prior to the due date/time, select the submission link from the home page and navigate to your submission.

Please note: For RPPs that are two stages (i.e. White Paper to Full Proposal) only the account that submitted the stage 1 proposal (the White Paper) will be allowed to submit for stage 2 (the Full Proposal), if selected.

ALL PROPOSALS MUST BE SUBMITTED BEFORE THE SUBMISSION DUE DATE AND TIME. LATE PROPOSALS CAN NOT BE ACCEPTED.