



MTEC
Medical Technology
Enterprise Consortium



BrightFocus[®]
Foundation

Cure in Mind. Cure in Sight

MTEC-20-16-mTBI

Proposal Preparation Manual

“Advancement of Drugs for the Treatment of Repeated Mild Traumatic Brain Injury (mTBI)”

Issued by:

Advanced Technology International (ATI)
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Summerville, SC 29486

For the
BrightFocus Foundation and
Medical Technology Enterprise Consortium (MTEC)

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1 General Instructions

Offerors must comply with the Request for Project Proposal preparation instructions specified in Solicitation # MTEC-20-16-mTBI, which references the content herein.

A proposal shall stand on its own merit. Only information provided in the proposal can be used in the evaluation process leading to an award. The proposal should be prepared simply and economically, providing straightforward, concise delineation of capabilities necessary to perform the work being proposed. Each Technical Proposal shall be accompanied by a detailed Cost Proposal, as well as a Project Schedule because cost and technical considerations are reviewed simultaneously.

DO NOT SUBMIT ANY CLASSIFIED INFORMATION. IF CLASSIFIED INFORMATION IS SUBMITTED IN A PROPOSAL, THE PROPOSAL MAY BE ELIMINATED!

Any export controlled technical data must be clearly identified on the cover page of the proposal. Export laws shall include but are not limited to the International Traffic in Arms Regulations (ITAR), the Export Administration Regulations (EAR), and the National Industrial Security Program Operating Manual (NISPOM).

The full proposal should include the following.

- **Technical Proposal:** one signed Technical Proposal (.pdf, .doc or .docx)
- **Statement of Work:** one Word (.docx or .doc)
- **Cost Proposal:** one Word (.docx or .doc) or PDF file for Section I: Cost Proposal and one Excel (.xlsx or .xls) file for Section II: Cost Proposal Formats

2 Technical Proposal

The Technical Proposal must address of the technical requirements described in Section 3 of the RPP in sufficient detail to permit evaluation from a technical perspective in accordance with the evaluation factors set forth in the RPP.

To ensure Technical Proposals receive proper consideration, **the Technical Proposal format shown below is mandatory.** If there are any items which are not applicable to a specific proposal, include the section topic in the proposal and annotate the section as not applicable with a short explanation as to why it is not applicable. All major sections listed below should be included in the Table of Contents:

- Cover Page
- MTEC Member Organization Information Sheet
- Table of Contents (include page numbers)
- List of Figures and Tables (include page numbers)
- Executive Summary
- Technical Approach
- Bibliography
- Appendices
 - A: Resumes of Key Personnel



- B: Letters of Support

The Technical Proposal (Volume 1) shall be limited to 15 pages.

The page limitation excludes the following:

- Technical Proposal Cover Page
- MTEC Member Organization Information Sheet
- Table of Contents
- List of Figures and Tables
- Bibliography
- Appendices

Pages in excess of this limitation may not be considered.

The Technical Volume must use 12 point font, be single-spaced, single-sided, (8.5 x 11 inches). Smaller type may be used in figures and tables, but must be clearly legible. Margins on all sides (top, bottom, left, and right) should be at least 1 inch. Offerors are strongly encouraged to use pictures and graphics to succinctly represent proposed ideas, organization, etc.

2.1 Technical Proposal (Volume 1) Cover Page

A Cover Page is required on the Technical Proposal (Volume 1), and must include the following information and statements:

Name and address of Offeror Title of proposal Volume 1 Technical Proposal
Statement that “This proposal is submitted pursuant to Request for Project Proposals MTEC-20-XX-XXXX”
Statement that “No export controlled technical data is included in this proposal” OR “ Export controlled technical data is included in this proposal in [list sections] ” (if the second statement is used, please set forth in red font).
Dates of submission and signature of official authorized to obligate the institution contractually.
The proprietary data disclosure statement, <u>when proprietary data is included.</u>



2.2 MTEC Member Information Sheet

An MTEC Member Information Sheet is required for the Technical Proposal (Volume 1) and must include the following information. If an item is not-applicable, then that section should be marked “not-applicable.” “References” refers to another funding sponsor for whom the proposing organization has conducted a research project, or someone who can attest to past performance.

MTEC Member Information Sheet Format

MTEC MEMBER NAME AND ADDRESS: (LIST ALL LOCATIONS WHERE WORK WILL BE PERFORMED)	
TITLE OF PROPOSED EFFORT:	
DUNS #:	
CAGE CODE:	
TAXPAYER ID # (TIN):	
BUSINESS SIZE/TYPE:	
PROPOSAL VALID TO (180 days from submittal):	
TOTAL COST OF PROPOSAL:	
PROPOSED PERIOD OF PERFORMANCE: _____ MONTHS AFTER AWARD (NOT TO EXCEED 60 MONTHS)	
USE OF ANIMAL SUBJECTS. (yes/no)	
USE OF HUMAN SUBJECT. (yes/no)	
USE OF HUMAN ANATOMICAL SUBSTANCES. (cell, tissue, etc.) (yes/no)	
USE OF COMMERCIAL/ PUBLICLY AVAILABLE CELL LINES. (yes/no)	
CADAVER USE. (yes/no)	
CONTRACT/NEGOTIATION CONTACT (NAME, ADDRESS, PHONE #, E-MAIL):	
TECHNICAL CONTACT (NAME, ADDRESS, PHONE #, E-MAIL):	
REFERENCE #1 (NAME, ORGANIZATION, PHONE NUMBER, EMAIL, CONTRACT #, CONTRACT AMOUNT, POP DATES, BRIEF DESCRIPTION OF WORK PERFORMED FOR REFERENCE):	
REFERENCE #2 (NAME, ORGANIZATION, PHONE NUMBER, EMAIL, CONTRACT #, CONTRACT AMOUNT, POP DATES, BRIEF DESCRIPTION OF WORK PERFORMED FOR REFERENCE):	
REFERENCE #3 (NAME, ORGANIZATION, PHONE NUMBER, EMAIL, CONTRACT #, CONTRACT AMOUNT, POP DATES, BRIEF DESCRIPTION OF WORK PERFORMED FOR REFERENCE):	

2.3 Table of Contents

Include page numbers in the table of contents.

2.4 List of Figures and Tables

This list is a quick reference of figures, table, charts, graphs, and other important information.

2.5 Executive Summary

The Executive Summary allows Offerors to briefly and concisely present the important aspects of their proposals to evaluators. The summary should present an organized progression of the work to be accomplished, without the technical details, such that the reader can grasp the core concepts of the proposed project. The Executive Summary is limited to no more than two pages.

2.6 Technical Approach

The “Technical Approach” section of the Technical Proposal **must include only** the requested information indicated below:

- **Approach:** [Describe the problem and your approach to solving the problem.]

- **Description of drug candidate:** [Describe the proposed drug candidate.]
- **Technology Readiness Level (TRL):** [Indicate the TRL stage in which the project will start and the expected TRL at the end of the period of performance (POP)].
- **Status to Date:** [Describe the current development status of the drug candidate. Include a robust description of the relevant preliminary/supportive data (results of prior studies) regarding your drug candidate that justifies its technical feasibility, current TRL, and its readiness to advance into human clinical trials in the near term.]
- **Objectives:** [Specify the objectives of the proposed effort of up to 24 months.]
- **Technical Strategy:** [Outline the proposed methodology by task in sufficient detail to show a clear course of action that addresses the technical requirements described in this RPP.]
- **Anticipated Outcomes:** [Provide a description of the anticipated outcomes from the proposed work. List milestones and deliverables from the proposed work.]
- **Clinical Indication:** [Describe all clinical indications already approved and/or planned for the product.]
- **Description of Follow-On Clinical Trial Plan:** [Although the clinical study will not be funded under this award, Offerors will be evaluated on the draft plan for their follow-on clinical study. This RPP is seeking drug candidates that have relevance to both the military and Alzheimer’s disease (AD) communities, however clinical studies should be focused on treatment of repeated, mTBI. Describe whether your clinical study will be designed to include a correlation to dementia/AD (NOTE: We are not seeking studies that include separate arms for TBI and AD, however, we are hoping that it is possible to utilize the data collected from TBI to correlate with the later onset of dementia/AD.) Provide anticipated clinical trial outcomes.]
- **Intellectual Property:** [Offerors should identify existing intellectual property (e.g., patents filed)].
- **Regulatory Pathway:** [A description and justification of the anticipated regulatory pathway and current status in the U.S. and/ or other countries, including completed and/ or planned regulatory milestones. (NOTE: If Offerors have had a pre-submission meeting with the FDA, include a description of the FDA’s feedback related to relevant issues such as classification and associated regulatory requirements, the clinical plan or clinical endpoints, and indication.)]
- **Commercialization Strategy:** [Provide a brief description of the commercialization plans to include both military and commercial markets.]
- **Military Impact:** [Offerors should demonstrate an understanding of the military need for therapeutic interventions for repeated, mTBI in a far-forward operational environment.]
- **Impact on AD:** [Offerors should provide logical reasoning with data (your own data or published literature) that suggests the linkage between treatment with the proposed drug candidate and the prevention of the later onset of dementia/AD.]
- **Participants:** [Briefly state the qualifications of the Principal Investigator, key personnel, and organizations that will perform the SOW.]
- **Schedule:** [Indicate the proposed POP. Provide a Gantt Chart of the major activities proposed.]
- **Cost Realism:** [This section provides technical evaluators with high-level cost data in order for them to determine if the costs proposed are realistic as compared to the scope of work proposed. This information must be consistent with the Cost Proposal. The information must be provided in this section of the Technical Proposal. Include the following table as a summary of the costs by task.]

Task Number	Task Name	Cost
Task 1		\$
Task 2 (if applicable)		\$
Task 3 (if applicable)		\$



TOTAL		\$
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2.7 Bibliography

There is no required format for the bibliography section.

2.8 Appendices

Appendix A: Resumes of Key Personnel (including Principal Investigator)

Include the resumes of key Lead MTEC member organization, team members, subcontractor and university personnel who will be assigned to and work on this project if selected. Indicate what percentage of their total available work time each will devote to this project.

Appendix B: Letters of Support

Include letters of support as appropriate. They act as an indication of market validation for the proposed innovation and add significant credibility to the proposed effort. Letters of support (no more than five) should demonstrate that the company has initiated dialog with relevant stakeholders (potential customers, strategic partners or investors) for the proposed innovation and that a real business opportunity may exist. The letter(s) must contain affiliation and contact information for the signatory stakeholder. Letters and supporting documents from consultants and subcontractors are NOT considered letters of support and are NOT to be included here. Letters and supporting documents from consultants and subcontractors should be included in the Budget Justification section.

3 Statement of Work

The Offeror is required to provide a Statement of Work (SOW) using the format here.

The SOW developed by the Lead MTEC member organization is intended to be incorporated into a binding agreement if the proposal is selected for award. The proposed SOW shall contain a summary description of the technical methodology as well as the task description, but not in so much detail as to make the contract inflexible. DO NOT INCLUDE ANY PROPRIETARY INFORMATION OR COMPANY-SENSITIVE INFORMATION IN THE SOW TEXT. The following is the required format for the SOW.

Statement of Work

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

(Proposed Project Title)

Introduction/Background

This section provides a brief background to the project.

Scope/Project Objective

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

Deliverables

It must be clear what information will be included in a deliverable either through a descriptive title or



elaborating text.

Milestone Payment Schedule (*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, and the monetary value for that deliverable. Since this will be a fixed price agreement, when each milestone is submitted, the MTEC member will submit an invoice for the exact amount listed on the milestone payment schedule.

The milestones and associated deliverables proposed should, in general:

- 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 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.
 - **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 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)

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

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MTEC Milestone Payment Schedule Example

MTEC Milestone Number	Task Number	Significant Event/ Accomplishments	Due Date	MTEC-BF Funds
1	N/A	Project Kickoff	12/1/2019	\$20,000
2	N/A	Quarterly Report 1 (October - December, Technical and Business Reports)	1/25/2020	\$ -
3	1	Protocol Synopsis	2/28/2020	\$21,075
4	2	Submission for HRPO Approval	2/28/2020	\$21,075
5	3	Submission of Investigational New Drug application to the US FDA	4/30/2020	\$210,757
6	N/A	Quarterly Reports 2 (January - March, Technical and Business Reports)	4/25/2020	\$ -
7	N/A	Quarterly Report 3 (April - June, Technical and Business Reports)	7/25/2020	\$ -
8	4	Toxicity Studies	10/1/2020	\$63,227
9	N/A	Annual Report 1	10/25/2020	\$ -
10	5	FDA authorization trial	11/30/2020	\$84,303
11	6	Research staff trained	11/30/2020	\$ -
12	7	Data Management system completed	11/30/2020	\$ -
13	8	1 st subject screened, randomized and enrolled in study	1/1/2021	\$150,000
14	N/A	Quarterly Report 4 (October - December, Technical and Business Reports)	1/25/2021	\$ -
15	9	Completion of dip molding apparatus	3/1/2021	\$ 157,829
16	N/A	Quarterly Reports 5 (January - March, Technical and Business Reports)	4/25/2021	\$ -
17	10	Assess potential toxicology	6/1/2021	\$157,829
18	N/A	Quarterly Report 6 (April - June, Technical and Business Reports)	7/25/2021	\$ -
19	11	Complete 50% patient enrollment	10/1/2021	\$350,000
20	N/A	Annual Report 1	10/25/2021	\$ -
21	N/A	Quarterly Report 7 (October - December, Technical and Business Reports)	1/25/2022	\$ -



22	12	Electronic Report Forms Developed	3/1/2022	\$315,658
23	N/A	Quarterly Reports 8 (January - March, Technical and Business Reports)	4/25/2022	\$ -
24	N/A	Quarterly Report 9 (April - June, Technical and Business Reports)	7/25/2022	\$ -
25	13	Complete 100% patient enrollment	8/1/2022	\$315,658
26	N/A	Annual Report 1	10/25/2022	\$ -
27	14	Report results from data analysis	11/1/2022	\$157,829
28	N/A	Final Reports (Prior to the POP End)	11/30/2022	\$ -
			Total	\$2,025,240

Please Note:

1. Cannot receive payment for a report (i.e., Quarterly, Annual and Final Reports should not have an assigned MTEC-BF Funded amount).
2. Quarterly and Annual Reports include BOTH Technical and Business Reports (separate).
3. Final Report due date must be prior to POP end noted in award.
4. MTEC Milestone Numbers are used for administrative purposes and should be sequential.
5. Task Numbers are used to reference the statement of work if they are different from the MTEC Milestone Number.

4 Cost Proposal

The objective of the Cost Proposal is to provide sufficient cost information to substantiate that the proposed cost is realistic, reasonable and complete for the proposed work. The Cost Proposal should provide enough information to ensure that a complete and fair evaluation of the reasonableness and realism of cost or price can be conducted and reflect the best estimate of the costs for the project. The Cost Proposal must be consistent with information provided in the Technical Proposal (i.e., costs, tasks, dates, etc.). NOTE: *Proposals that deviate substantially from these guidelines or that omit substantial parts or sections may be found non-responsive and may be eliminated from further review and funding consideration.*

To ensure Cost Proposals receive proper consideration, it is mandatory that the Cost Proposal include the information below.

Section I: Cost Proposal Narrative

- a. Cover Page
- b. MTEC Member Organization Information Sheet
- c. Table of Contents
- d. Budget Narrative

Section II: Cost Proposal Formats



4.1 Section I: Cost Proposal Narrative

There is no page limit for the Cost Proposal Narrative.

A Cover Page is required on the Cost Proposal (Volume 2), and must include the following information and statements:

<p>Name and address of Offeror Title of proposal Volume 2 Cost Proposal</p> <p>Statement that "This proposal is submitted pursuant to Request for Project Proposals MTEC-20-XX-XXX"</p> <p>Dates of submission and signature of official authorized to obligate the institution contractually.</p> <p>The proprietary data disclosure statement, <u>when proprietary data is included.</u></p>



An MTEC Member Information Sheet is required for the Cost Proposal (Volume 2) and must include the following information. If an item is not-applicable, then that section should be marked “not-applicable.” “References” refers to another funding sponsor for whom the proposing organization has conducted a research project, or someone who can attest to past performance.

MTEC Member Information Sheet Format

MTEC MEMBER NAME AND ADDRESS: (LIST ALL LOCATIONS WHERE WORK WILL BE PERFORMED)	
TITLE OF PROPOSED EFFORT:	
DUNS #:	
CAGE CODE:	
TAXPAYER ID # (TIN):	
BUSINESS SIZE/TYPE:	
PROPOSAL VALID TO (180 days from submittal):	
TOTAL COST OF PROPOSAL:	
PROPOSED PERIOD OF PERFORMANCE: _____ MONTHS AFTER AWARD (NOT TO EXCEED 60 MONTHS)	
USE OF ANIMAL SUBJECTS. (yes/no)	
USE OF HUMAN SUBJECT. (yes/no)	
USE OF HUMAN ANATOMICAL SUBSTANCES. (cell, tissue, etc.) (yes/no)	
USE OF COMMERCIAL/PUBLICLY AVAILABLE CELL LINES. (yes/no)	
CADAVER USE. (yes/no)	
CONTRACT/NEGOTIATION CONTACT (NAME, ADDRESS, PHONE #, E-MAIL):	
TECHNICAL CONTACT (NAME, ADDRESS, PHONE #, E-MAIL):	
REFERENCE #1 (NAME, ORGANIZATION, PHONE NUMBER, EMAIL, CONTRACT #, CONTRACT AMOUNT, POP DATES, BRIEF DESCRIPTION OF WORK PERFORMED FOR REFERENCE):	
REFERENCE #2 (NAME, ORGANIZATION, PHONE NUMBER, EMAIL, CONTRACT #, CONTRACT AMOUNT, POP DATES, BRIEF DESCRIPTION OF WORK PERFORMED FOR REFERENCE):	
REFERENCE #3 (NAME, ORGANIZATION, PHONE NUMBER, EMAIL, CONTRACT #, CONTRACT AMOUNT, POP DATES, BRIEF DESCRIPTION OF WORK PERFORMED FOR REFERENCE):	

Additionally, a Table of Contents must be provided.

The Budget Narrative is used to assess various criteria. This section will be used to determine reasonableness, allowability, and allocability of costs. The Budget Narrative section should provide a more detailed breakdown of the figures that are contained in the Cost Proposal Formats. The Budget Narrative section also should give substantiation and written explanation of proposed costs. Breakdowns should be as accurate and specific as possible. Ensure that any figures presented in this part are consistent with the figures in the Cost Proposal Formats.

The Budget Narrative must include, at a minimum, details on the following cost categories for the proposed cost:

Labor Rates. In the Cost Proposal Formats section, the Offeror should identify the position title of all personnel and hourly rate and show estimated hours for each labor category proposed. If this information is not contained in the Cost Proposal Formats section, then it must be included in the Budget Narrative section. **If the Offeror’s approved organizational estimating procedures use average labor rates for specific labor categories, this would be acceptable.** It is recognized that an organization may not be able to identify all of the personnel to be assigned to the project several years in advance. Where this cannot be done, use generic position titles such as “engineer.” If direct labor costs include allocated direct costs or other direct costs in accordance



with the Offeror's established accounting and estimating practices and systems, identify these costs separately and provide an explanation and basis for proposed costs in the Budget Narrative section. Note that rate and pricing information is required to properly perform the cost analysis of a proposal. Proposals without this information cannot be properly evaluated and may be eliminated from selection for award.

Fringe Benefits. In the Budget Narrative, identify percentage rate and, if greater than 40 percent and the organization does not have Government certified rates, Offerors may be asked to provide substantiation. Percentage rates may not exceed 50% percent.

Team Members/Subcontractors. A cost by cost element breakout for each of the team members/subcontractors proposed must be provided in the Cost Proposal volume either as part of the Budget Narrative or the Cost Proposal Formats. Team member/subcontractor proposals should be as detailed as possible, but at a minimum should include the following: labor categories and hours specified, list of material/equipment and other direct costs, travel detail, lower tier subcontractors/consultants identified, indirect costs. In the Budget Narrative, please provide a list of all team members/subcontractors and a total cost for each team member. **Offeror also must state that a cost and price analysis has been performed on all team members/subcontractors and their proposed costs found to be fair and reasonable.**

Consultants. A cost by cost element breakout (i.e., labor categories, associated hours, travel, other direct costs, etc.) for each of the consultants proposed must be provided in the Cost Proposal volume either as part of the Budget Narrative or the Cost Proposal Formats. In the Budget Narrative, provide a list of all consultants and a total cost for each consultant. **Offeror must state that a cost and price analysis has been performed on all consultants and their proposed costs found to be fair and reasonable.**

Material/Equipment. An itemized list of the material/equipment proposed including the cost must be provided in the Cost Proposal volume either as part of the Budget Narrative or the Cost Proposal Formats. Provide a basis of cost (i.e., vendor quote, catalog pricing data, past purchase orders, etc.) for each item. **Additionally, a copy of the basis of cost documentation for each piece of proposed material/equipment with a unit cost greater than or equal to \$50,000 must be included in the Offeror's Cost Proposal.** The value of equipment should be prorated according to the share of total use dedicated to carrying out the proposed work. Include a brief explanation of the prorating methodology used. Offerors must submit an affirmative statement that all proposed material/equipment was proposed in accordance with its approved costing procedures.

Travel. The Offeror must provide an estimate of the travel required for the proposed effort broken out by participant (i.e., Offeror's and any team member's/consultant's travel schedule) either in the Budget Narrative or the Cost Proposal Formats. **Travel may be estimated based on the Offeror's approved methodology.** Estimate the number of trips; cost per trip; number of days; number of persons; destination; approximate travel time frames; and the purpose of the travel. The key is to apply best estimating techniques that are auditable. Include a brief explanation of the methodology used to estimate travel costs. Note that MTEC project awardees are expected to be cost-conscious regarding travel (e.g., using coach rather than first class accommodations and, whenever possible, using Government per diem, or similar regulations, as a guideline for lodging and subsistence costs).

Other Direct Costs. The Offeror must identify and provide an itemized list including cost and a



detailed description of any other direct costs that do not fit into the cost categories above, including the basis for determining those costs (i.e., vendor quotes, catalog pricing data, company estimating procedures, etc.) either in the Budget Narrative Section or the Cost Proposal Formats. **Additionally, a copy of the basis of cost documentation for each piece of proposed other direct cost with a unit cost greater than or equal to \$50,000 must be included in the Offeror's Cost Proposal.**

Indirect Costs. Indirect costs are not allowed under this funding mechanism. If you have an identifiable costs specific to the proposed scope of work that are typically designated as indirect costs, you may include these as direct costs.

Total Cost by Major Task/Clinical Study Cost Elements. When required by the Solicitation. In the Budget Narrative, include a list of each major task that is stated in the Statement of Work and its associated total cost. The sum of the major tasks must equal the total listed in the Cost Proposal Formats. It is recommended that the number of major tasks be kept to the minimum number required to manage the project effectively.

4.2 Section II: Cost Proposal Formats

The Cost Proposal Formats provided are mandatory. The Cost Proposal Format section of the proposal must include a **breakout of the total cost proposed by cost element** for each year of the program. Supporting data and justification for labor, equipment/ material, team member/subcontractor, consultants, travel, other direct costs, and indirect costs used in developing the cost breakdown also must be included. The Offeror must provide sufficient details to allow a full understanding of and justification for the proposed costs. Offerors must refer to the RPP for a start date for cost estimating purposes.

The Cost Proposals Formats include a Total Project Cost sheet, a Subcontractor/Consultant detail sheet, a Material Equipment detail sheet, a Travel detail sheet, an Other Direct Costs detail sheet, and a Costs by Major Task sheet. The MTEC Cost Proposal Formats in Microsoft Excel can be obtained from the MTEC members only website.

The Solicitation may require costs be broken out by Major Task which would be identified in the RPP. If so, costs should be broken out for each Major Task that is stated in the Statement of Work. The cost formant should reflect estimated costs for each task by year, as well as totals for the entire project. The sum of the major tasks must equal the total of the total costs. It is recommended that the number of major tasks be kept to the minimum number required to manage the project effectively

5 Additional Requirements

5.1 Prohibition of Use of Human Cadavers

Research, development, testing and evaluation (RDT&E), education or training activities involving human cadaveric specimens under a Research Project Award shall not begin until approval is granted in accordance with the local Institutional Review Board (IRB).

The Research Project Awardee must promptly report problems related to the conduct of the activity involving cadavers or the procurement, inventory, use, storage, transfer, transportation, and disposition of cadavers to the MTEC/BrightFocus Foundation Technical Lead(s).



The Research Project Awardee must maintain complete records of the activity.

The MTEC, BrightFocus Foundation or designees must be permitted to observe the activity upon request and/or audit activity records to ensure compliance with the approved protocol or applicable regulatory requirements.

Non-compliance with these terms and conditions may result in withholding of funds and/or the termination of the award.

5.2 Prohibition of Use of Human Subjects

Research under this Agreement or Research Project Awards involving the use of human subjects, to include research involving the secondary use of human biospecimens and/or human data, cannot begin until the local IRB provides authorization that the research may proceed. The IRB will issue written approval to begin research under separate notification to the Research Project Awardee, a copy of which shall be provided to the appointed MTEC/BrightFocus Foundation Technical Lead(s).

Accurate and complete study records must be maintained and made available to the funding organizations as a part of their responsibility to protect human subjects in research. Research records must be stored in a confidential manner so as to protect the confidentiality of subject information.

The Consortium is required to adhere to the following reporting requirements:

Submission of substantive modifications to the protocol, continuing review documentation, and the final report..

Unanticipated problems involving risks to subjects or others, subject deaths related to participation in the research, clinical holds (voluntary or involuntary), and suspension or termination of this research by the IRB, the institution, the Sponsor, or regulatory agencies, must be promptly reported to the funding organizations.

Change in subject status when a previously enrolled human subject becomes a prisoner must be promptly reported to the funding organizations.

The knowledge of any pending compliance inspection/visits by the FDA concerning this clinical investigation or research, the issuance of Inspection Reports, FDA Form 483, warning letters or actions taken by any Regulatory Agencies, and any instances of serious or continuing noncompliance with regulatory requirements that relate to this clinical investigation or research, must be reported immediately to the funding organizations.

Non-compliance with these terms and conditions may result in withholding of funds and/or the termination of the award.

5.3 Prohibition of Use of Laboratory Animals

Research Project Awardees (or lower tier subawards) are expressly forbidden to use laboratory animals in any manner whatsoever without the express written approval of the local Institutional Animal Care and Use Review Committee (IACUC). Written authorization to begin research under the applicable protocol(s) proposed for Research Project Award(s) must be provided to the funding organizations. Furthermore, modifications to already approved protocols require approval by the IACUC to the Research Project Awardee(s), a copy of which shall be provided to the appointed MTEC/BrightFocus Foundation Technical Lead(s).

Non-compliance with any of these terms and conditions may result in withholding of funds and/or the termination of the Research Project Award.



5.4 Technical Representative and Alternate

(The following information will be provided by the MTEC.)

5.5 MTEC Royalty Agreement or MTEC Additional Assessment Fee

Each Research Project Award recipient shall pay MTEC an amount equal to 1% of the total funded value of the award. Such deposits shall be due no later than 90 days after an invoice is received from MTEC. This invoice will be issued after the award is executed or subsequent funding has been provided. Awardees are not allowed to use MTEC funding to pay for their assessment fees. Additionally, MTEC has established two methods of payment to be made to MTEC surrounding the licensing/commercialization of Intellectual Property developed with funding received from MTEC Research Project Awards:

Royalty Payment Agreements

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

Additional Research Project Award Assessment

In lieu of providing the royalty payment agreement described above, members receiving Research Project Awards may elect to pay an additional assessment of 2% above the standard assessment percentage described in Section 3.4 of the CMA.



ATTACHMENT 1 – COST PROPOSAL FORMATS

To download the Cost Proposal Formats in Excel format, log-in to the Members Only section of the MTEC website.