The *Panacea* Team

- Dr. Tristan McClure-Begley, Program Manager
- Ms. Elizabeth Kilpatrick, Financial and Administrative Support
- Dr. Gina Kost, Technical Support
- Dr. Zach Poss, Technical Support

Contracting Support

- Peter Donaghue, Contracting Officer
- Dr. Stephanie McElhinny, Contracting Officer’s Representative

All correspondence to: Panacea@darpa.mil
Procedures

• We recommend you have a hardcopy of the Panacea BAA in front of you.
• Send any questions after the Proposers day to Panacea@darpa.mil.
  • We will answer all questions via the FAQ (more details on the FAQ will be provided during the “BAA Inbox and Submission” presentation).
The problem we wish to solve

DoD Problem: Human physiology is a limiting factor in military operational readiness.

Highly specific drugs designed for one molecular target often result in a moderate physiological effect.

Human physiology is complex and involves multiple “targets” and diverse functional pathways.

Reductionist Approach

Drug Target Protein
Physiological Phenotype

Effect

Conventional Targeted Drug

Pharmacology Systems Approach

Drug Target Protein
Physiological Phenotype

Effect

Multi-target drug → maximum physiological benefit
### Why do we (DoD) care?

#### Mitigating Metabolic Stress

**SoA:** Stimulants (e.g., Modafinil).

#### Controlling Pain and Inflammation

**SoA:** Supportive care (e.g., Casts, physical therapy, opiates), surgical repair and traditional medications (e.g., NSAIDS, antibiotics, etc.).

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Preparation warfighter physiology for the demands of the future.
DARPA seeks to develop new technological approaches in medicinal chemistry and systems pharmacology to expand the druggable proteome and discover new therapeutic tools in the areas of soft tissue pain/inflammation and metabolic stress that limit optimal physiological function. *BAA pg. 3*

Goals:
- Unlock 98% of the cell as possible targets to assist rapid resilience and recovery.
- Platform technology that can be adapted to multiple physiological conditions and performance environments.
- Demonstrate superior effectiveness for areas such as mitigating effects of metabolic stress (e.g. resulting from exertion, acute/chronic illness) and targeted control of pain without addiction.

It is up to you to propose a solution.
The BAA breaks the problem down into two “Technical Tasks.”

Task 1. Predict and Evaluate Drug Targets and Effects

Task 2. Novel Intervention Design

Your proposal must address both tasks

You may propose a research plan for no more than 5 years.

Phase I 24 months

Phase II 24 months

Phase III 12 months
Panacea Program Overview

Optimize human physiological performance by accelerating drug development.

<table>
<thead>
<tr>
<th>Task 1: Predict and Evaluate Drug Targets and Effects</th>
<th>Task 2: Novel Intervention Design</th>
</tr>
</thead>
<tbody>
<tr>
<td>Profile physiological system and build computational tools to process data, inform experimental design, and determine targets (known &amp; unknown) for drug design and refinement.</td>
<td>Use novel chemical synthesis methods to work around current drug target structure-function limitations.</td>
</tr>
<tr>
<td>• Identify network</td>
<td></td>
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<tr>
<td>• Reduce target space</td>
<td></td>
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<tr>
<td>• Evaluate drugs</td>
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</tbody>
</table>

Demonstrations: Improve and/or Restore Function In Vivo
**Task 1: Predict and Evaluate Drug Targets and Effects**

**Interrogate physiological model systems to identify druggable targets.**

Deep profiling technologies allow us to measure everything in a cell.

- **Multi-omics**
- **f(x) Analytics**

Find actionable sets of protein targets

**Evaluate novel drugs for safety and efficacy.**

High-throughput assays to confirm mechanism of action

Preclinical safety/efficacy (therapeutic index)
Computational elements of the program – Task 1

**Key computational approaches for Panacea goals:**

Task 1: Predict and evaluate drug targets and effects

- “Informatics Components – computational approaches to enable empirically guided network construction to identify and define actionable sets of protein targets.” *BAA pg. 6*
- “The informatics effort will develop and use computational tools to generate directed networks of physiological processes incorporating all molecular and phenotypic data.” *BAA pg. 6*

Statistically well-designed bioinformatics efforts should be used in physiological systems to construct complex networks, define actionable targets within those networks, and profile the physiological system over a phenotypic gradient in a temporal manner.

- Data curation: “All raw data, metadata and informatics analyses and tools specific to each experiment must be made available and curated. All data (raw data, highly-detailed metadata and key analysis files) from multi-omics experiments will be uploaded to an appropriate server and be widely available (e.g., GEO and/or PRIDE for sequencing and proteomic data, respectively). Software design will be well-documented, and analyses must be systematically documented with coding tools (e.g., *Jupyter* notebook) for evaluation and reproducibility.” *BAA pg. 7*

This is a large bioinformatics effort that will require substantial documentation and comprehensive curation.
Task 2: Novel Intervention Design

Develop novel drug synthesis for the known and unknown target space.

Develop novel tools to accelerate the pace of drug design.

Design and Build Molecules

Optimize Drug Activity

Approved for Public Release, Distribution Unlimited
Approaches and tools that will NOT be considered

1. Existing proprietary chemical compounds or capabilities

2. Gene editing or intervention at the genetic level

3. Model systems not explicitly designed or validated as organism-level preclinical models

4. Drug repurposing efforts

_BAA pg. 9_
Table 1: Program Schedule and “Demonstrations”

<table>
<thead>
<tr>
<th>Technical Task</th>
<th>Phase 1 (24 Mo)</th>
<th>Phase 2 (24 Mo)</th>
<th>Phase 3 (12 Mo)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Task 1: Predict and Evaluate</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Task 2: Novel Intervention Design</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Demos</th>
<th>End of Phase 60 Day Final Exam:</th>
<th>End of Phase 60 Day Final Exam:</th>
<th>End of Phase 60 Day Final Exam:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physiotypic Model System Test Run</td>
<td>60 days to network assembly and identification of targets</td>
<td>30 days to validate targets</td>
<td>Demonstrating Standard Care <em>in vivo</em></td>
</tr>
<tr>
<td>Final Exam Test Run In Vivo</td>
<td>Build drug design infrastructure</td>
<td>30 days to build and test new drug candidate</td>
<td>IND Submission</td>
</tr>
<tr>
<td>Intermediate In Vivo Demo</td>
<td></td>
<td></td>
<td>Examine options for compassionate use</td>
</tr>
<tr>
<td>Final Exam Test Run In Vivo</td>
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<tr>
<td>Restoration or Enhancement In Vivo</td>
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</tbody>
</table>

**Guidance**

- Use this table as a guide to how you structure your technical plan and metrics by phase
## Milestones and Metrics: Table 2

| Phase 1: 24 Months | **Milestone:** Previously unknown drug targets for metabolic stress and/or pain/inflammation.  
**Metrics:**  
- **Step 1:** Build a functional network of >10,000 proteins and >500 protein-protein interactions quantified for multiple cell types in >2 tissues specific to indication.  
- **Step 2:** Define drug targets from functional protein networks.  
- **Mid-Phase Exam (month 12):** Show 80% coverage of canonical network and additional target space.  
- **Task 1 Demo (month 24):** Drug target space for metabolic stress and/or pain/inflammation in <60 days.  
- **Task 2 Demo (month 24):** Generate ≥30 small molecule candidates targeting protein networks for metabolic stress and pain/inflammation. |
|-------------------|-------------------------------------------------------------------------------------------------|
| Phase 2: 24 Months | **Milestone:** Functioning pipeline with *in vivo* validation of novel drug mechanism.  
**Metrics:**  
- **Task 1 Mid-Phase Exam (month 36):** Validation of novel network by predicting and testing new drug combinations: e.g. 1) Improved function and/or tolerance under metabolic stress; 2) Control pain/inflammation post-insult model better than single drug therapy  
- **Task 2 Mid-Phase Exam (month 36):** Demonstration of target engagement for novel multi-target drugs.  
- **Task 1 Demo (month 48):** 30 days to network assembly and intervention identification for known/unknown targets.  
- **Task 2 Demo (month 48):** Synthesis platform to build novel drugs <30 days after target space definition. |
| Phase 3: 12 months | **Milestone:** Multi-target drug for metabolic stress and/or pain/inflammation with effectiveness exceeding state of the art.  
**Metrics:**  
- **End of Program Goal (month 60):** Novel multi-target drug with therapeutic index (toxic dose/effective dose) 1.5-2x greater than standard of care.  
  - Effect onset in 2-40 minutes, duration of 12-24 hours without repeat dosing.  
  - Drug interacts with >2 protein of previously unknown function.  
  - Preclinical data for Pharmacology and Toxicology for IND.  
  - Transition strategy and/or corporate partner for entry into clinical trial. |

**Guidance:** You must address everything in this table. You may also (and should) come up with additional, intermediate milestones and metrics, by task and phase, to gauge your progress.
Prior to the end of each phase, a demonstration of program progress is required. It is not required that proposers set aside a specific period of time for a demonstration, rather, the demonstration should be a test of the platform capability by the end of the phase.

At the end of the phase, the outcomes of the demonstration experiments should be presented to DARPA and invited representatives of other government agencies as a concise research study. Lab demonstrations of how the technology works, animal/human results/effects, and illustration of system integration are all expected. High-level information on the nature of the approach, mechanistic understanding, and how the challenge conditions conceptualize a real-world application for the approach(es) should be the major foci of the presentation.
Panacea
Doing Business with DARPA

Peter Donaghue
Contracting Officer
DARPA Contracts Management Office

12/14/18
Abstract and Full Proposal Tips

Proposal Abstract Tips

• Abstracts are strongly encouraged, but optional
• Abstracts are limited to 8 pages
• DARPA will respond to abstracts with a statement as to whether DARPA is interested in receiving a full proposal
• You may submit a full proposal even if you did not submit an abstract

Full Proposal Tips

• Read the BAA carefully - Nonconforming proposals may be rejected without review
• Task 1 and Task 2 for all Phases (I, II, III) proposal requirements listed in Sections 1.1 through 1.4 and under 4.2.2
• Full Proposal Vol I is limited to 35 pages
• You may submit a full proposal even if a proposal is discouraged in response to your abstract
Read the BAA carefully - Nonconforming proposals may be rejected without review.

There is no page limit to Volume II Cost Proposal.

Cost break downs are outlined in the BAA:
- By Phase (I, II, III) by contractor fiscal year
- Total program cost by major task: Task 1 and Task 2
- Projected funding required by month (account for early equipment needs)

Subcontractor proposals must be prepared at the same level of detail as that required of the prime.

Don’t forget travel funds for key personnel to attend the Kickoff Meeting and semi-annual PI Review meetings.

See BAA pg. 22-24 for details regarding the detailed cost proposal guidance.
All responsible sources capable of satisfying the Government's needs may submit a proposal that shall be considered by DARPA.

Non-U.S. organizations and/or individuals:
- Non-U.S. organizations and/or individuals may participate to the extent that such participants comply with any necessary nondisclosure agreements, security regulations, export control laws, and other governing statutes applicable under the circumstances.

Government Entities & FFRDC’s: subject to limitations:
- Government agencies/labs, FFRDCs cannot propose to this BAA in any capacity, UNLESS they can clearly demonstrate the work is not otherwise available from the private sector AND they also provide written documentation citing the specific statutory authority (as well as, where relevant, contractual authority) establishing their eligibility to propose to government solicitations.

Organizational Conflicts of Interest:
- DARPA policy: Without prior approval or a waiver from DARPA, in accordance with FAR 9.5, a contractor cannot simultaneously provide scientific, engineering, technical assistance (SETA) or similar support (A&AS) and also be a technical performer.
- Must address in your proposal if providing SETA or similar support to any DARPA technical office(s) through an active contract or subcontract.
Full Proposal Review-Awards Process

- No common Statement of Work - Proposals are evaluated on individual merit and relevance as it relates to the stated research goals/objectives rather than against each other
- Proposals are evaluated for strengths and weaknesses relative to the criteria published in the BAA, listed in descending order of importance:
  - Overall Scientific and Technical Merit
  - Potential Contribution and Relevance to the DARPA Mission
  - Cost Realism
- Government reserves the right to select for award all, some (partial selection), or none of the proposals received.
- Government anticipates making multiple awards

- **Contract negotiation timelines depend on each institution/organization’s responsiveness to the proposal requirements in the BAA.**

- The contracting office will contact the selected performers and begin the contracting process.

See BAA pg. 29-31 for details regarding proposal evaluation
Responding to the BAA
Important Dates

- Posting Date: December 10, 2018
- Proposal Abstracts are due by Monday, Jan. 7, 2018, 4:00 PM ET
- Full Proposals are due by Friday, Feb. 22, 2018, 4:00 PM ET
- BAA Closing Date: Friday Feb. 22, 2018
Important, but approximate dates

- Full Proposals Due 22 February
- Selected for funding
- Contract negotiations
- Funds arrive

~45 days
~60-90 days
"Proposers must present a plan for no more than five years and a comprehensive approach to meeting all program milestones." BAA pg. 5

Assuming satisfactory progress,

- We anticipate funding 1 or 2 performers teams for all five years.
- We do not plan to down-select performers.
- Funding for subsequent Phases is contingent on the availability of funds.
Abstracts are strongly **encouraged**, but optional.

Abstracts should include:
- Executive Summary
- Goals and Impact
- Technical Plan
  - *Be sure to address all Tasks by Phase.*
  - *Be sure to include milestones*
- Capabilities (Management plan)
  - Identify the Principal Investigator (PI)
  - Responsibilities of the team members
- Cost and Schedule

Abstracts limited to 8 pages (excluding cover page).

*For more details see BAA section 4.2.1*

DARPA will respond to abstracts with a statement as to whether DARPA is interested in receiving a full proposal.

You may submit a full proposal even if you did not submit an Abstract.
Nonconforming proposals may be rejected without review.

Volume I - Technical and Management Proposal

A. Executive Summary {1-2 pages}
B. Goals and Impact {1-2 pages}
C. Technical Plan {12-15 pages}
   
   *Be sure to address all Technical Tasks*
   
   *Describe your technical approach, rationale, schedule (Gantt), challenges and risks*
D. Management plan {2-3 pages}
   
   *Identify the PI, key personnel, and their roles*
E. Capabilities {1-3 pages}
F. Statement of Work (SOW) {3-6 pages}
G. Schedule and Milestones {1-3 pages}
H. Transition Plan {0.5-1 pages}
I. Summary Slide {2 slides; attachment}

Full proposals limited to 35 pages (plus 1 page each for the cover sheet and official transmittal letter).

*For more details see BAA section 4.2.2*

• While the end of program milestones are prescribed by DARPA, proposers must provide intermediate milestones for all Technical Tasks.
The Review Process

- Scientific Review by government personnel from DARPA, ARO, FDA, and other USG agencies.

- Proposals are not ranked, but evaluated for strengths and weaknesses with respect to the criteria published in the BAA:
  a) Overall Scientific and Technical Merit
  b) Potential contribution and relevance to DARPA mission
  c) Cost realism

- Program Manager recommends proposals for funding.

See BAA for details regarding the evaluation criteria.
To fully address the BAA you *might* (?) need to team with other entities.

- If you need to build a team across multiple institutions/subcontractors, you must present a convincing and justifiable demonstration of collaborative capability:
  - You must find your collaborators on your own.
  - Your team should submit a unified proposal under a single PI.
  - This BAA is open to educational institutions, government labs, and/or private companies.
  - Foreign entities may join a team or submit as the PI.
  - If you are a member of a team, you may join any number of other teams or form your own and submit a proposal as PI.
  - Note that the cost volume for each team member must be at the same level of detail as for the PI.
  - “Proposals should include...100% project manager for the entirety of the effort.” BAA pg.9
Final bits of advice

• Read the BAA over and over again and follow all instructions carefully.

• A successful proposal addresses all aspects of the BAA.
  • Pay attention to “must”, “should”, “shall”, and “all” in the BAA.
  • Incomplete proposals will not be evaluated.

• Do not try to shoehorn ongoing, but not applicable, work into the BAA.

• Do not submit a rewritten NIH or NSF proposal.

• Do not propose to do anything that is not directly relevant to the BAA.

• Do not submit an irrelevant or incomplete proposal in the hope we’ll fund it anyway.

• A proposal abstract is highly recommended. We cannot stress this enough!
How DARPA thinks about your project

Science & Engineering

Good science

Your proposal

Today

Program Goal

Good science
Panacea BAA Process Overview—BAA Inbox and Submission

David Swan III
BAA Coordinator
DARPA Biological Technologies Office

12/14/2018
Direct all questions and communications to the Panacea BAA Inbox:

Panacea@darpa.mil

Dr. McClure-Begley cannot provide feedback or guidance on any aspect of your proposal, nor can any member of his team or the BAA Inbox. They can only clarify the content of the Panacea BAA.

A FAQ will be available on the DARPA Opportunities web page:


The FAQ will be updated regularly prior to the proposal submission deadline, however all questions must be submitted **at least 15 days prior** to the deadline.
Before submitting a question, you should…

Read the BAA.

Understand that you’ll get a clarification, not an idea.

Re-read the BAA.

Understand that you won’t get any information from a competitor.

Study the BAA.

Understand that your question will likely be added to the FAQ.

MEMORIZE THE BAA!!!
Submission Specifics

NO submissions via fax/e-mail

Cooperative Agreements – Grants.gov

All other Award Instruments – DARPA BAA Portal (https://baa.darpa.mil)

Start Today 😊

Only include attachments requested in the BAA
Final Submission Advice

Read the BAA over and over again and follow all instructions carefully.

A conforming proposal addresses all aspects of the BAA:
- Pay attention to “must”, “should”, “shall”, and “all” in the BAA.
- Nonconforming proposals may not be evaluated.

**DO NOT** try to shoehorn ongoing, but not applicable, work into the BAA.

**DO NOT** submit a rewritten NIH or NSF proposal.

**DO NOT** propose to do anything that is not directly relevant to the BAA.

**DO NOT** submit an irrelevant or incomplete proposal in the hope we’ll fund it anyway.

A proposal abstract is **HIGHLY RECOMMENDED**
Highly Recommended Budget Template
Attachment - DARPA-BAA-HR001119S0010
Benefits of using the Panacea BAA Budget Template

- Whether proposers choose to use this template or not, the Panacea BAA asks them to provide all the information the template asks for:
  - “The Government encourages proposers to complete an editable MS excel budget template…” ([DARPA-BAA-HR001119S0010, Section 4.2.2])

- “(1) Please submit any breakdown of expenses in an editable, MS EXCEL cost file.
  - (2) Total program, per phase, and per task cost broken down by major cost items to include:
    - **Direct labor** - provide an itemized breakout of all personnel, listed by name or TBD, with labor rate (or salary), labor hours (or percent effort), and labor category. All senior personnel must be identified by name.
    - **Materials and Supplies** - itemized list which includes description of material, quantity, unit price, and total price […].
    - **Equipment** - itemized list which includes description of equipment, unit price, quantity, and total price […].
    - **Animal Use Costs** - itemized list of all materials, animal purchases, and per diem costs, associated with proposed animal use; include documentation supporting daily rates.
    - **Travel** - provide an itemized list of travel costs to include purpose of trips, departure and arrival destinations, projected airfare, rental car and per GSA approved diem, number of travelers, number of days); […] Conference attendance must be justified, explain how it is in the best interest of the project […].
    - **Other Direct Costs (e.g., computer support, clean room fees)** - Should be itemized with costs or estimated costs […].
    - **Other Direct Costs** - Consultants: provide executed Consultant Agreement that describes work scope, rate and hours.
    - **Indirect costs** including, as applicable, fringe benefits, overhead, General and Administrative (G&A) expense, and cost of money (see university vs. company specific requirements below).
      - **Indirect costs specific to a University performer:** (1) Fringe Benefit Rate […]; (2) F&A Indirect Overhead Rate […]; (3) Tuition Remission […]; and (4) Health Insurance/Fee […].
      - **Indirect costs specific to a Company performer:** (1) Fee/Profit […]; and (2) Fringe Benefit/Labor OH/Material OH/G&A Rates […].

- “(3) A summary of total program costs by phase and task; (4) An itemization of Subcontracts. All subcontractor cost proposal documentation must be prepared at the same level of detail as that required of the prime […]; (5) An itemization of any information technology (IT) purchase […]; (6) A summary of projected funding requirements by month for all phases of the project; (7) A summary of tasks that have animal or human use funding.”
  - ([DARPA-BAA-HR001119S0010, Section 4.2.2])
Key Excel Concepts & Tutorial Videos

• The template can be easily customized to reflect the structure of each proposers’ particular project
• The budget template is already formatted to reflect the 2-task and 4-phase structure of the Panacea program
• Key MS Excel Concepts
  • Linking data within tabs
  • Linking data across tabs
  • Absolute reference
• Contact the Panacea BAA Inbox with any questions
  • Panacea@darpa.mil
General Structure of Template

<table>
<thead>
<tr>
<th>High-level Summary Tabs</th>
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<tbody>
<tr>
<td>Cost Proposal Summary</td>
</tr>
<tr>
<td>Summary by Phase</td>
</tr>
<tr>
<td>Summary by Task</td>
</tr>
<tr>
<td>Milestones and Deliverables</td>
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<tr>
<th>Detailed data-entry tabs linked together</th>
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<tr>
<td>Phase I, II, and III</td>
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<tr>
<td>Prime Travel</td>
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<td>Prime ODCs</td>
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<td>Subcontractor Budget</td>
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<td>- Subcontractor Travel</td>
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<td>Prime Labor Rates</td>
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<td>Prime Materials-Supplies</td>
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<td>Expenditures by Month</td>
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<td>Animal and Human Use</td>
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<tr>
<th>Other Essential Information</th>
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<td>- Grey Cells: Data Entry</td>
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<td>- White Cells: Formula</td>
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<td>- Proposers can edit any cell (data or formula) as necessary to fit this template to the structure of their specific project. Proposers can leave any non applicable field blank, delete it, or hide it.</td>
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<thead>
<tr>
<th>This budget CANNOT form the entire cost proposal</th>
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<tbody>
<tr>
<td>- Read the entirety of DARPA-BAA-HR001119S0010 , Section 4.2.2</td>
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<tr>
<td>- Will still need to provide additional information to agent if selected for award</td>
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</table>
Cost Proposal Summary Tab

- Add requested information to rows 4-9
- Rows 10-37 contain formulas that link to data from the “Summary by Task” and “Summary by Phase” tabs
- Unless substantial edits are made to the template, it will likely be unnecessary to edit the formulas in this tab

<table>
<thead>
<tr>
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<td>Panacea Cost Proposal Summary</td>
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<td>Period of Performance</td>
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<td>11</td>
<td>Phase 1/Base</td>
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<td>Phase 2/Option 1</td>
<td>24 months</td>
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<td>Phase 3/Option 2</td>
<td>12 months</td>
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<td>22</td>
<td>Phase 2/Option 1 Total</td>
<td>$</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>23</td>
<td>Phase 3/Option 2 Total</td>
<td>$</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>24</td>
<td>Total Project Cost</td>
<td>$</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>25</td>
<td>Prime vs. Subcontractor Cost</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>26</td>
<td>Total Prime</td>
<td>$</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>27</td>
<td>Total Subcontractor</td>
<td>$</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>28</td>
<td>Cost Per Category</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>29</td>
<td>Personnel &amp; Benefits</td>
<td>$</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>30</td>
<td>Supplies</td>
<td>$</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>31</td>
<td>Equipment</td>
<td>$</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>32</td>
<td>Subcontractors</td>
<td>$</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>33</td>
<td>Animal Related</td>
<td>$</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>34</td>
<td>Sub-Total: Direct Costs</td>
<td>$</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>35</td>
<td>Sub-Total: Indirect Costs</td>
<td>$</td>
<td>-</td>
<td></td>
</tr>
</tbody>
</table>

Approved for Public Release, Distribution Unlimited
• Provides totals for each major cost item (e.g., labor, equipment, subcontractors, etc.) for each task, each phase, and the total project

• Links to data from the “Phase” tabs

• Unless substantial edits are made to the template, it will likely be unnecessary to edit the formulas in this tab
### Summary by Task Tab

- Provides totals for task and subtask per phase and for the total project
- Links to data from the “Phase” tabs
- Unless substantial edits are made to the template, it will likely be unnecessary to edit the formulas in this tab

<table>
<thead>
<tr>
<th>Task #</th>
<th>Descriptive Text</th>
<th>Total</th>
<th>Task #</th>
<th>Descriptive Text</th>
<th>Total</th>
<th>Task #</th>
<th>Descriptive Text</th>
<th>Total</th>
<th>All Phases</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Task 1: Predict and Evaluate</td>
<td>$</td>
<td>1</td>
<td>Task 1: Predict and Evaluate</td>
<td>$</td>
<td>1</td>
<td>Task 1: Predict and Evaluate</td>
<td>$</td>
<td>$</td>
<td>#DIV/0!</td>
</tr>
<tr>
<td>2</td>
<td>Task 2: Novel Intervention Design</td>
<td>$</td>
<td>2</td>
<td>Task 2: Novel Intervention Design</td>
<td>$</td>
<td>2</td>
<td>Task 2: Novel Intervention Design</td>
<td>$</td>
<td>$</td>
<td>#DIV/0!</td>
</tr>
<tr>
<td></td>
<td>Travel and ODCs</td>
<td>$</td>
<td></td>
<td>Travel and ODCs</td>
<td>$</td>
<td></td>
<td>Travel and ODCs</td>
<td>$</td>
<td>$</td>
<td>#DIV/0!</td>
</tr>
<tr>
<td>Total</td>
<td>$</td>
<td></td>
<td>Total</td>
<td>$</td>
<td></td>
<td>Total</td>
<td>$</td>
<td></td>
<td>$</td>
<td>#DIV/0!</td>
</tr>
</tbody>
</table>

**Cell Color Legend:**
- **DataEntry**
- **Formula**

You can edit any cell (data or formula) as necessary to fit the template to the structure of your specific project. You can leave any non-applicable field blank, or delete it.
**Coupled very closely with the technical proposal and statement of work (SOW)**

- Defines the following for tasks/subtask of the project:
  - Description
  - Exit criteria/metrics
  - Milestones
  - Deliverables
  - Start/end dates
  - Milestone and deliverable due dates
Phase Tabs

- Data entered and calculated in to these tabs will feed in to the summary sections of the budget
- The budget template is already formatted to reflect the 2-task and 3-phase structure of the Panacea program
- Majority of cells in the “Phase” tabs are white/blue, which means that a majority of the cells are calculated
- Asks for a breakdown of the following major cost items:
  - Labor and Benefits
  - Supplies
  - Equipment
  - Animal related
  - Subcontractors
- By:
  - Item name
  - Description
  - Cost
  - Unit description
  - How much is being applied to each task
Phase Tab Walkthrough

Insert descriptive information and cost per item – this will be used to calculate totals for task 1 and 2

Summarizes major cost items

Once the effort/quantity is entered the total cost per task will be calculated from the effort/unit cost

---

<table>
<thead>
<tr>
<th>Item Name</th>
<th>Item Description</th>
<th>Effort/Unit Cost</th>
<th>Unit</th>
<th>Effort/Qty</th>
<th>Cost</th>
<th>Effort/Qty</th>
<th>Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Summary</td>
<td></td>
<td>0.00</td>
<td></td>
<td>0.00</td>
<td></td>
<td>0.00</td>
<td></td>
</tr>
<tr>
<td>Personnel + Benefits</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Supplies</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Equipment</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Human/Animal Related</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Subcontractors</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sub-Total: Direct Costs</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Material Handling Overhead</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Capital equipment</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tuition</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Subcontractor costs greater than 25,000 per subcontractor</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sub-Total Exclusions</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Modified Total Direct Costs</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sub-Total: Indirect Costs (F&amp;A or G&amp;A)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cost of Money (for contracts only)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fee (for contracts only)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total Costs</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| Personal            |                                                     | 0.00             |      | 0.00       |      | 0.00       |      |
| Benefits            |                                                     |                  |      |            |      |            |      |
| Supplies            |                                                     |                  |      |            |      |            |      |
| Equipment           |                                                     |                  |      |            |      |            |      |

---

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Phase Tab Walkthrough

### Summary

<table>
<thead>
<tr>
<th>Item Name</th>
<th>Item Description</th>
<th>Effort/Unit Cost</th>
<th>Unit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Personnel + Benefits</td>
<td>Supplies</td>
<td>$</td>
<td>Unit</td>
</tr>
<tr>
<td>Equipment</td>
<td>Human/Animal Related</td>
<td>$</td>
<td>Unit</td>
</tr>
<tr>
<td>Subcontractors</td>
<td>Sub-Total: Direct Costs</td>
<td>$</td>
<td>Unit</td>
</tr>
<tr>
<td>Only applicable to Companies: Material Handling Overhead</td>
<td>Only applicable to Universities: Indirect Costs (F&amp;A or G&amp;A)</td>
<td>$</td>
<td>Unit</td>
</tr>
<tr>
<td>Less Exclusions: (if applicable: insert exclusions specific to your institution)</td>
<td>Cost of Money (for contracts only)</td>
<td>$</td>
<td>Unit</td>
</tr>
<tr>
<td>Capital equipment</td>
<td>Fee (for contracts only)</td>
<td>$</td>
<td>Unit</td>
</tr>
</tbody>
</table>

**All Tasks**

<table>
<thead>
<tr>
<th>Effort/Qty</th>
<th>Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.00</td>
<td>$</td>
</tr>
</tbody>
</table>

Calculates the total per phase cost once effort/quantity is entered for each task.
**Example – Personnel**

1. Enter person’s name and title (e.g. PI) [Cells A28 and B28]
2. Enter person’s rate [Cell C28]
3. Assign level of effort to each task (e.g., PI is working 25% time on Task 1) [Cell F28]
4. Cost automatically calculated for task total [Cell G28]
5. Enter benefit percentage rate [Cell C33]
6. Benefit cost automatically calculated [Cell G33]
7. Personnel cost for Task 1 and 2 automatically calculated for entire phase [Phase Total Column]
**Example – Supplies**

1) Enter supply name and description [Cells A38 and B38]
2) Enter unit cost [Cell C38]
3) Assign quantity to each subtask (e.g., 10 units for task 1) [Cell F38]
4) Cost automatically calculated for task [Cell G38]
5) Supplies cost for Task 1 and 2 automatically calculated for entire phase [Phase Total Column]
Travel and ODCs pull data from the “Prime Travel” and “Prime ODCs” tabs.

These data series are examples of costs that do not cleanly fit beneath a task and subtask.

- You don’t need to arbitrarily assign travel and ODC costs to tasks and subtasks.
The level of detail illustrated above is required for negotiations.

We understand that it is difficult to plan for DARPA-specific travel because the meeting dates, duration, and location are TBD.

- Estimate to the best of your ability
- Meetings will be domestic, there will be a registration fee
- Pull lodging and M&I&E rates from the GSA website
- Conference attendance needs to be supported with a very strong justification of how it is in the best interest of the project
Costs that do not cleanly fit under a task or subtask
- Examples include rental fees, shipping costs, license fees, facilities usage rates, FACS usage rates, gene synthesis costs, sequencing costs

- Provide a description, quantity, unit of issue, and cost for each phase
- Should be used sparingly

### Program-Admin Costs (ODCs) Tab

**Other Direct Costs (ODCs): Program or Administrative Costs**

**for any costs that do not cleanly fit under a task/subtask**

Examples include rental fees, shipping costs, license fees, facilities usage rates, FACS usage rates, gene synthesis costs, sequencing costs

<table>
<thead>
<tr>
<th>Description</th>
<th>Quantity (#)</th>
<th>Unit of Issue (e.g., dozen, gallon, pair, pound, ream, set, yard)</th>
<th>Unit Price</th>
<th>Total Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase 1/Base</td>
<td>$</td>
<td>$</td>
<td>$</td>
<td>-</td>
</tr>
<tr>
<td>Phase 2/Option 1</td>
<td>$</td>
<td>$</td>
<td>$</td>
<td>-</td>
</tr>
<tr>
<td>Phase 3/Option 2</td>
<td>$</td>
<td>$</td>
<td>$</td>
<td>-</td>
</tr>
<tr>
<td>Total</td>
<td>$</td>
<td>$</td>
<td>$</td>
<td>-</td>
</tr>
</tbody>
</table>

**Note 1:**
Provide as an attachment all supporting documentation to support explanation of how the engineering estimate was derived
Prime Labor and Indirect Rate Tabs

- These tabs are not linked to other tabs in the template
- The agent will need to clearly understand how labor rates escalate throughout the project
- The agent will need to clearly understand how fringe benefits, labor overhead, material handling, G&A, facilities cost of money, and/or any other indirect rate(s) are applied throughout the project

**Prime Labor Rate Information**

<table>
<thead>
<tr>
<th>Personnel Name</th>
<th>Labor Category</th>
<th>Year 1 Escalation Rate</th>
<th>Year 2 Escalation Rate</th>
<th>Year 3 Escalation Rate</th>
<th>Year 4 Escalation Rate</th>
<th>Year 5 Escalation Rate</th>
<th>Basis of Labor Rate</th>
</tr>
</thead>
</table>

**Prime Indirect Rate Information**

<table>
<thead>
<tr>
<th>Rate Category</th>
<th>Year 1 Rate</th>
<th>Year 2 Rate</th>
<th>Year 3 Rate</th>
<th>Year 4 Rate</th>
<th>Year 5 Rate</th>
<th>Basis of Rate (Example: FPRA, FPRP, Estimate, etc.)</th>
<th>Applied Against</th>
</tr>
</thead>
</table>
- Please provide an itemized breakdown of all materials/supplies/consumables and equipment
The “phase” tabs apply total subcontractor costs to tasks and subtasks to understand how the costs are applied to the overall project; however, the government still needs a separate, itemized breakout of subcontractor costs.

**Recommended Use**
- **<$500,000 per phase:** use format illustrated above
- **>$500,000 per phase:** use more detailed “phase” tab format
### Expenditures by Month Tab

<table>
<thead>
<tr>
<th>Prime Name</th>
<th>PI Name</th>
<th>Expenditures by Month</th>
</tr>
</thead>
</table>

#### Phase 1/Base
- **Length:** 24 months
- **Calendar Year:**
  - 2015
  - 2020
  - 2021
- **TOTAL:** $-

#### Phase 2/Option 1
- **Length:** 24 months
- **Calendar Year:**
  - 2021
  - 2022
  - 2023
- **TOTAL:** $-

#### Phase 3/Option 2
- **Length:** 12 months
- **Calendar Year:**
  - 2023
  - 2024
- **TOTAL:** $-

- Important and very helpful for the government’s internal planning purposes
- Try to make the data as accurate as possible
  - Consider increases/decreases in spend rate rather than simply dividing the cost for a given phase by the months in a given phase
Designed to easily display what tasking has animal and human use associated with it.
Animal Research at DARPA

2018
According to the DoD, an animal **IS**

- A living or dead **vertebrate**
- A larval fish or amphibian
- An egg-laying vertebrate is only an animal **after hatching**
What is not an Animal?

An animal is **NOT**

- An un-hatched egg
- An invertebrate
- Dead animals or parts of dead animals purchased at grocery stores or slaughterhouses
ALL Animal Research in the US Must Follow

1. Animal Welfare Act/Animal Welfare Regulations
2. Guide for the Care and Use of Laboratory Animals

DARPA animal research must also follow

3. DoD Instruction 3216.01 “Use of Lab Animals in DoD Programs”
   Applies to all animal research conducted or supported by the DoD

These regulations are available on the web
DoD vet approval is needed **before** any money can be awarded for animal related expenses.

---

**Animal Related**

- **Food**
- **Housing**
- **Purchase of animals**

**Non - Animal Related**

---

Other questions about your contract? Contact your contract officer!
All DARPA animal use protocols must go through two reviews.

1st review: Local Level (IACUC Review)

2nd review: DoD Level (Secondary Review)
The Reviews

- All animal use protocols in the USA must be approved by an IACUC.
- International research must be approved by their IACUC equivalent.

In addition, all DoD funded animal use must also be approved by a DoD vet.

DARPA funded animal use protocols are reviewed by a DoD vet at MRMC Animal Care and Use Review Office (ACURO).
### Required Submission Docs
- IACUC approved protocol
- Evidence of IACUC approval
- Most recent USDA report
- ACURO appendix
  - Available on ACURO’s website

### Approval Process
- ACURO reviews docs
- May ask PI for clarifications
- Sends to DoD vet for final review and approval

**Approval takes 2-3 months**

ACURO approval is good for the length of the award or length of IACUC approval

Distribution Statement A
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All amendments to protocols (including minor) must also go through two reviews prior to implementation.

1st review
Local Level (IACUC Review)

2nd review
DoD Level (Secondary Review)

There is **NO EXCEPTION** to this policy
Review of Amendments

After amendments are approved by the IACUC and sent to ACURO:

**Minor Amendments**
Require administrative review
1-3 days for approval

**Major Amendments**
Require veterinary review
1-2 weeks for approval

After amendments are approved by ACURO, the changes described can be implemented.
If amendments are implemented before ACURO review, the research is **NONCOMPLIANT**

Noncompliance may be cause to cancel the contract!
Take Home Messages

1. If a protocol involves animal research, it must follow DoD animal use regulations

2. All animal use protocols require TWO approvals

3. All amendments must be reviewed by ACURO
DARPA’s Animal Use POC is here to help with all aspects of animal research at DARPA including:

- Approval process
- Acting as liaison between PIs, PMs, agents, and ACURO
- Locating and understanding regulations
- Any other animal use questions or issues

Animal Use POC
Carrie Lewis
Carrie.Lewis.ctr@darpa.mil
703-526-1439