

Request for Project Proposal (RPP)

Solicitation Number: HT942726RE020

**Prototype development for Battlefield
Wound Infection Prevention and
Treatment (BWI P&T) Barrier
Combination**

Issued by the:

Defense Health Agency Contracting Activity (DHACA)
808 SCHREIDER ST
FORT DETRICK MD 21702

for the:

Defense Health Agency (DHA)
Portfolio Acquisition Executive Medical Products (PAE MP)
Warfighter Protection and Acute Care
Project Management Office
(WPAC PMO)

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1. Executive Summary

1.1 Request for Project Proposal (RPP)

This RPP is being issued by the Defense Health Agency Contracting Activity (DHACA), in support of the Defense Health Agency's Portfolio Acquisition Executive (PAE) Medical Products (MP) Warfighter Protection (WPAC) & Acute Care Program Management Office (PMO) Care located in Frederick, Maryland at Fort Detrick. The Warfighter Protection and Acute Care Project Management Office (WPAC PMO) has a requirement for the development of a Barrier Combination product. The Barrier Combination product is defined as being composed of both a physical barrier to protect a wound and an antibacterial and/or antifungal activity released from the barrier to prevent the spread of organisms and avoid systemic infections.

This RPP will result in one award to develop the Battlefield Wound Infection Prevention and Treatment (BWI P&T) Barrier Combination (BC) prototype product.

The final product MUST be a combination wound treatment that includes a barrier component that is either infused or impregnated with antimicrobial and/or antifungal properties and have U.S. Food Drug Administration (FDA) approval (or clearance).

The award, as a result of this RPP, will be awarded under the authority of prototype Other Transaction Authority (pOTA) 10 U.S.C. 4022.

1.2 Background

The BWI P&T program is focused on identifying potential medical products for maturation that can prevent and treat infections in wounds sustained in combat. Current battlefield wound management care is governed based on the possibility of timely evacuation of wounded Service Members to a higher echelon of care. However, it is anticipated that future combat operations will require prolonged casualty care rather than immediate evacuation. Organisms commonly cultured from BWI include both bacterial and fungal species, and some are difficult to treat with currently available therapies. In addition, current fielded products require increased treatment frequency, target a limited number of organisms, are not effective against common drug-resistant pathogens, and have limited suitability throughout the entire continuum of care. The identification of novel solutions to address the needs of the Joint Force to prevent and treat BWI, especially as it pertains to counteracting emergent and/or drug-resistant organisms, would significantly enhance the preparedness of the warfighter for future combat operations.

1.3 Inclusion of Nontraditional Defense Contractors or Nonprofit Research Institutions

10 U.S.C. 4022 authorizes Department of Defense organizations to carry out prototype projects that are directly relevant to enhancing the mission effectiveness of personnel of the Department of Defense or improving 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. To use this authority for an agreement resulting from this

RPP, one of the following conditions must be met:

(A) There is at least one (1) nontraditional defense contractor or one (1) non-profit research institute participating to a “*significant extent*” in the prototype project.

or

(B) All “*significant*” participants in the transaction, other than the Federal Government, are small businesses or nontraditional defense contractors.

or

(C) At least one third (1/3) of the total cost of the prototype project is to be paid out of funds provided by parties to the transaction other than the Federal Government. NOTE: One statutory condition for the use of a pOTA is if the performing team does not include either a Non-Traditional Defense Contractor (NDC) or a small business concern participating to a “*significant extent*” in the prototype project, when this occurs, it is then required to have at least 1/3 of the total cost of the prototype project to be paid by the parties, other than the Federal Government.

Definitions:

Non-Traditional Defense Contractor (NDC) – An entity that is not currently performing and has not performed, for at least one-year period preceding the solicitation of sources by DoD for the procurement or transaction, any contract or subcontract for the DoD that is subject to full coverage under the cost accounting standards (CAS) prescribed pursuant to section 1502 of title 41 and the regulations implementing such section (see 10 U.S.C. §3014). The phrase “the solicitation of sources” refers to the initial agreement solicitation only. A nontraditional defense contractor is considered a nontraditional defense contractor for the duration of the prototype project/agreement’s period of performance, or for any in-scope work modified under the same agreement.

NOTE: Per the statutory definition, NDCs are all entities that have not performed under a narrowly defined set of circumstances within one year of solicitation of the current OT opportunity. The effect of this narrow definition is that many entities will fall into the NDC category, including nearly all small business concerns, and even those firms that work exclusively with DoD. This is in part due to the exemptions to CAS coverage under 41 U.S.C. §1502 and FAR Part 30, which exempt commercial contracts, Firm Fixed Price contracts based on adequate price competition, and any contract or subcontract with a small business concern, among other exemptions. Further, even where an entity is not outright exempt from CAS coverage, the entity may not have been subject to “full” CAS coverage. This is because full CAS coverage applies only to firms that receive a single CAS-covered contract award of \$50 million or more; or received \$50 million or more in net CAS-covered awards during its preceding cost-accounting period.

1.4 System for Award Management (SAM) Registration

System for Award Management (SAM.gov) is a centralized web-based tool used by the federal Government’s executive agencies as the authoritative source for federal awardee data. SAM Entity Information module maintains annually self-reported entity information including address and contact information, banking information, and representations and certifications.

Companies and other organizations who are prime awardees for Other Transition (OT) agreements MUST register in SAM and maintain an active registration status throughout performance. The prime awardee MUST use its Unique Entity Identifier (UEI) from SAM (<https://sam.gov>). If NAICS code 541715 “Research and Development in the Physical, Engineering, and Life Sciences (except for Nanotechnology and Biotechnology)” is not currently listed in the Performer’s SAM.gov account, it MUST be added prior to award.

2. Requirement Overview

2.1 Award Type

The Government prefers a Firm Fixed Priced (FFP) type pOTA. However, a cost-plus fixed fee (CPFF) is acceptable.

2.2 Period of Performance

The estimated period of performance (PoP) for the entire effort is 54 months.

The estimated PoP for Objective 1 is 24 months.

The estimated PoP for Objective 2 is 24 months.

The estimated PoP for Objective 3 is 6 months.

NOTE: The government anticipates that Objectives 1 & 2 may be conducted simultaneously or overlapping for a period of several months but not to exceed 48 months. The remaining six (6) months are to account for pending FDA review and approval (or clearance) (Objective 3).

2.3 Frequency of funds obligated

The pOTA is anticipated to be incrementally funded. An incremental funding schedule will be provided at time of award.

2.4 Proprietary Information

DHACA will oversee submission of the proposal submitted in response to this RPP. DHACA will take the necessary steps to protect all proprietary information and will not use such proprietary information for purposes other than the evaluation of an Offeror’s proposal and the subsequent agreement administration if the proposal is selected for award in accordance with Federal laws and regulations.

Additionally, all Technical Evaluation Panel participants will agree to and sign a non-disclosure and conflict of interest documents.

2.5 Intellectual Property (IP)

Intellectual Property (IP) rights for this award will be defined in the negotiated terms and conditions (i.e. Articles) of the Agreement. As a starting reference point, the

Government's standard IP terms have been provided. See **Article 7, 8 and 9** of the Agreement's terms & conditions.

Prior to award, the selected awardee will be required to provide the Government with a list and brief description of any background IP related to the research and development activities contemplated under the proposed agreement, which will be incorporated into the Agreement. The list includes relevant IP such as:

- (1) Relevant issued U.S. and foreign patents, which the presumptive awardee partially or wholly owns or is an assignee;
- (2) All relevant pending U.S. patent applications, provisional patent applications, PCTs that have not yet expired, and any foreign patent applications, including national stage applications, which the presumptive awardee partially or wholly owns or is an assignee;
- (3) Relevant copyrighted/copyrightable works/material in which the presumptive awardee has rights in;
- (4) Relevant patent/copyright licenses that the presumptive awardee is party to;
- (5) Any relevant patents, patent applications, and/or copyrights owned by third parties that the presumptive awardee has knowledge of; and
- (6) Any license with a third party for technology that is or may be necessary for the presumptive awardee to use in order to perform or meet obligations under this Agreement.

2.6 Preliminary Screening & Eligibility

The Government will conduct a preliminary screening of submitted proposals to ensure compliance with the RPP submission instructions. As part of the preliminary screening process, the Government reserves the right to request additional information or simply eliminate the proposal that was not proposed in accordance with the RPP submission instructions. Additionally, preliminary screening and eligibility also include the following:

- Written confirmation that the Offeror will serve as the FDA Sponsor for this development effort per 21 C.F.R. 312 Subpart D, and other applicable FDA regulations, guidance, and International Conference on Harmonization (ICH) guidance. Written confirmation must include the Sponsor Indication Form FDA 1571 (**see Attachments D1 and D2**).
- Filled out **Attachment F** "Warranties and Representations."

NOTE: One of the primary reasons for non-compliance or elimination during the preliminary screening, is not properly demonstrating that Offeror is a nontraditional defense contractor (NDC), nonprofit research institution, or not cost sharing (if applicable).

The Offeror must submit Warranties and Representations (**Attachment F**) specifying the critical technologies being offered and/or the *significant extent* of participation of the NDC or nonprofit

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research institution or cost share (if applicable). The NDC may be an individual so long as he/she has a SAM.gov UEI and meets the requirements in the Warranties and Representations. The significance of the NDC's or nonprofit research institution's participation must be explained in detail in the signed Warranties and Representations.

To be eligible for award, a proposal must demonstrate that at least one (1) of the following conditions are met:

Rating	Description
Pass	(A) Demonstrated that there is at least one (1) nontraditional defense contractor or one (1) non-profit research institute participating to a significant extent in the prototype project. or (B) Demonstrated that all significant participants in the transaction, other than the Federal Government, are small businesses or non-traditional defense contractors. or (C) Demonstrated at least one third (1/3) of the total cost of the prototype project is to be paid out of funds provided by parties to the transaction other than the Federal Government. NOTE: One statutory condition for the use of a Prototype OT is if the performing team does not include either a NDC or a small business concern participating to a "<i>significant extent</i>" in the prototype project, when this occurs, it is then required to have at least 1/3 of the total cost of the prototype project to be paid by the parties, other than the Federal Government.

Rating	Description
Fail	(A) Did NOT demonstrate that there is at least one (1) nontraditional defense contractor or one (1) non-profit research institute participating to a significant extent in the prototype project. or (B) Did NOT demonstrate that there all significant participants in the transaction, other than the Federal Government, are small businesses or nontraditional defense contractors. or

	(C) Did NOT demonstrate at least one third (1/3) of the total cost of the prototype project is to be paid out of funds provided by parties to the transaction other than the Federal Government
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3. Proposal Preparation Instructions

3.1 General Instructions

This section provides general guidance for preparation of the proposal as well as specific instructions on the format and content of the proposal. The proposal submitted must contain three (3) separate volumes. **Volume I: Technical, Volume II: Management, and Volume III: Administrative and Cost** and must be submitted in accordance with these General Instructions. If an Proposer fails to submit their proposal in accordance these instructions, the Government may reject the entire proposal and may not be evaluated for award.

The Proposer's proposal must include all requested data and information and must be submitted in accordance with the instructions in this solicitation. If the Proposer does not submit their proposal in accordance with the RPP instructions, the Government reserves the right to request additional information or simply eliminate the proposal entirely if not proposed in accordance with these Section 3.1 General instructions.

The proposal must be clear, concise, and must include sufficient detail for effective evaluation and for substantiating the validity of stated claims. The proposal must not simply rephrase or restate the Government's requirements, but rather must provide convincing rationale to address how the Proposer intends to meet these requirements. Government evaluators will not assume that the Proposer possess any capability unless it is specified in the written proposal and will base its evaluation solely on the information presented in the Proposer's proposal.

Elaborate brochures or documentation, binding, detailed artwork, or other embellishments are unnecessary and not desired.

If the Proposer believes that the requirements in these instructions contain an error, omission, or are otherwise unsound, the Proposer must immediately notify the DHACA Agreements Specialist, listed in this RPP, in writing, with supporting rationale.

3.2 Organization of Proposal

General

The Proposer must prepare the proposal as set forth in the Proposal Organization Table below. The titles and contents of each volume must contain the documents as indicated in the Proposal Organization Table. The three (3) separate and distinct volumes are:

Volume I: Technical;
Volume II: Management; and
Volume III: Administrative & Cost

Proposal Organization Table

Volume	Section Title	Page Limit
Volume I: Technical	Cover Page (with POC contact information)	2 pages
	Table of Contents	1 page
	Technical Approach: - Non-clinical and clinical studies/trials that will be conducted and the associated process to be obtained/achieved to support submission to the FDA for approval of the Barrier Combination product.	20 pages
	- Attachment H – Statement of Work (SOW) & Milestones template.	No page limit
Volume II: Management	Cover Page	2 pages
	Table of Contents	1 page
	Management Approach: - Project Management Plan (PMP) with Integrated Master Schedule (IMS) (including Risk Management Plan, Staffing Plan, Subcontractor Management Plan and Teaming Agreement (if applicable), and Work Breakdown Structure. - Commercialization Plan, and - Regulatory Strategy	20 pages
	Teaming Agreement (if applicable)	No page limit
Volume III: Administrative and Cost/Price	Cover Page	2 pages
	Table of Contents	1 page
	Attachment D - Sponsor Indication Form 1571	N/A
	Attachment F – Warranties and Representations	N/A
	- Attachment 6 (of the Agreement) – Foreign Disclosure Agreement -Disclosure of same or similar scope of work -Disclosure of previous SBIR work	N/A
	Attachment G1 – FFP with milestones or Attachment G2 Cost Sheet Templates with milestones	N/A
	Written Cost Narrative (with support documentation)	No page limit
	Accounting System capability & POCs for DCMA/DCAA (if applicable)	1 page

Submission Format

Each volume must be submitted electronically in searchable PDF format. For the Project Management Plan (PMP) in addition to a high-level presentation in PDF format as part of the Volume I: Technical submission, the Offeror must submit an electronic copy in Microsoft Project with milestones and tasks. The files must be virus and malware free and must not be password protected. Files must not include hyperlinks. The electronic submission must be compatible with Microsoft Office and Adobe Acrobat.

Volume Content

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Each volume must be written on a standalone basis. Each volume must contain a cover page and table of contents. Each page must be numbered and include the RPP number and Offeror name. For Volume 1 Technical cover page, please be sure to include a point of contact with the authority to negotiate on behalf of the Proposer. The information in each volume must be specific and complete as well as legible, clear, and concise. Per the instructions, the Proposer must provide as specifically as possible, the actual methodology it proposes to use to accomplish and satisfy all requirements. By submitting a proposal, the Proposer represents that it will be responsible for meeting the requirements specified in the solicitation.

Labeling

To request protection from the Freedom of Information Act (FOIA) Section 552 of title 5, U.S.C., disclosure as allowed by 10 U.S.C. 4022), the Proposer shall mark business plans and technical information with a legend identifying the documents as being submitted on a confidential basis.

3.3 Volume I: Technical

Technical Approach

The Proposer must submit a written technical approach which effectively demonstrates the Proposer's clear understanding and approach to achieving all of the objectives outlined in the SOO. In addition to the written technical approach, the Proposer must also describe non-clinical and clinical studies that will be conducted and the associated process to be obtained/achieved to support submission to the FDA for approval of an Barrier Combination product as well as a Statement of Work (SOW) with milestones. The SOW with milestones shall include all necessary tasks and align with the Integrated Master Schedule (IMS).

Proposers must include technical and corporate experience that reflect the ability to execute the SOO. Any relevant experience achieving FDA clearance / approval and commercializing must also be included.

Attachment H - SOW – The Proposer must fill out and submit **Attachment H** - Statement of Work & Milestones template. The Proposer must fill in the specific tasks to be completed for each objective (see last page of **Attachment H**). The SOW must include all the necessary tasks required to accomplish the SOO and align with the IMS. **The Offeror's SOW is the primary document detailing the tasks proposed.**

3.4 Volume II: Management

Management Approach

The Proposer must submit a written management approach which effectively demonstrates the Proposer's clear understanding and approach to achieving all of the objectives outlined in the SOO. The management approach consists of: Project Management Plan (PMP) with Integrated Master Schedule (IMS) including Risk Management Plan, Staffing Plan, Subcontractor Management Plan (if applicable), Work Breakdown Structure, Commercialization Plan, and Regulatory Strategy.

Project Management Plan (PMP) (Deliverable 9 of the SOO)

The Proposer must provide a PMP detailing the approach to managing the project schedule, project risks, cost control, testing timeline and includes sufficient detail to allow the Government to assess

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overall management strategy and project control measures. The PMP must include an Integrated Master Schedule (IMS), including Risk Management Plan, Project Staff selection, Subcontractor Management Plan and Teaming Agreement (if applicable) and Work Breakdown Structure (WBS).

(a) Integrative Master Schedule (IMS)

The Proposer MUST provide a detailed IMS specifying developmental plans to the proposed device/system. The IMS shall address what the anticipated steps are and overall timelines in order for all components of the Proposer's proposed prototype. Throughout each task period of performance, the Proposer MUST update the IMS monthly with any changes.

(b) Risk Management Plan -

The Proposer must provide a risk management plan that identifies significant risks to project success, root cause of the risk, the impact and probability of risk realization, and mitigation strategies for each risk.

(c) Project Staffing Plan

The Proposer must include an itemized list of number of labor positions with associated job titles who will be working on the proposed effort and how they intend to retain and recruit additional staff, if needed.

(d) Subcontractor Management Plan (if applicable)

The Proposer must provide a Subcontractor Management Plan that describes how the Proposer will identify, select, manage, and oversee subcontractors to ensure successful execution of the requirement. The plan must be concise, complete, and tailored to the proposed effort. This includes consultants as well.

(d)(1) Teaming Agreement (if anticipated)

The Offeror must include evidence (e.g statement of intent to enter into a teaming agreement/subcontractor, if subcontractor(s) are proposed.

NOTE: Proposers who propose consultants, subawardee(s) and/or contractual arrangements with foreign organizations or foreign collaborators must provide additional justification explaining why the foreign organization or foreign individual can carry out the scope of work more effectively than a U.S. organization or U.S. individual.

(e) Work Breakdown Structure (WBS)

The Proposer must provide a work breakdown structure that organizes tasks and provides a clear roadmap for project execution. The WBS must be clearly defined, including deliverables and tasks.

Commercialization Plan (Deliverable 6 of the SOO)

Describes the company's strategy to generate revenue and business opportunities, outlines a strategy to move candidate product(s) into the Market, and describes current and anticipated market landscape and resources required to address the opportunity of the candidate product.

Regulatory Strategy (Deliverable 3 of the SOO)

The Proposer must submit a regulatory strategy for FDA approval/clearance. The regulatory strategy must be described in sufficient detail to allow the Government to assess the appropriateness of the strategy, probability of success, and regulatory risks. Describe and outline the critical regulatory pathways and objectives to ensure adequate planning to bring a new product

to market as well as the overall sustainability and the product end of life.

3.5 Volume III: Administrative and Cost/Price Volume

Attachment D – FDA Form 1571

The Proposer must submit written confirmation that the Offeror will serve as the FDA Sponsor for this development effort per 21 C.F.R. 312 Subpart D, and other applicable FDA regulations, guidance, and International Conference on Harmonization (ICH) guidance. Written confirmation must include the Sponsor Indication Attachment D - Form FDA 1571.

Attachment E – DRAFT Agreement (Terms and Conditions)

The DRAFT agreement is being provided for situational awareness. The Government will provide a tailored DRAFT Agreement once a Performer is selected and the selected Performer will have an opportunity to negotiate terms and conditions with the Government.

Attachment F - Warranties and Representations

The Proposer must fill in and submit **Attachment F - Warranties and Certifications**. (Reference Section 1.3 & 2.6 of the RPP)

Attachment G1 – FFP Template

The Proposer must fill in and submit the FFP Template if they are proposing a firm fixed price solution. All formulas and calculations must be included for review. The FFP template must show the proposed dollar value for entire effort, including fully burdened pricing with accurate calculations.

Attachment G2 – Cost Sheet Template (i.e. expenditure-based)

The Proposer must fill in and submit the CPFF Template if they are proposing an expenditure-based (i.e. cost reimbursement) solution. All formulas and calculations must be included for review. The CPFF template must show proposed dollar values for the entire effort, including all direct and indirect costs and fees, where applicable, with accurate calculations.

Cost/Price

The Proposer must submit **both** a written cost estimate and fill out and submit **Attachment G1 – FFP Template or Attachment G2 – Cost Template**. All budget information must be addressed ONLY in Volume III: Administrative and Cost/Price. Do not address cost/price in Volume I Technical or Volume II Management. The cost/price information submitted under Volume III: Administrative must include the government provided FFP or CPFF template, showing all formulas and links, including applicable subcontractor budget.

NOTE: Estimated levels of effort, labor hours, labor positions, consultant services, travel, material/supplies, quantities, etc. may be referenced/addressed in Volume I Technical and Volume II Management, but **no** cost/price information may be used in Volume I Technical and Volume II Management.

Compliance with these instructions is mandatory and failure to comply may result in rejection of the Proposer's proposal. Unrealistically low or unreasonably high proposed costs, initially or subsequently, may be grounds for considering the proposal unacceptable, either on the basis

that the Proposer does not understand the requirement or has otherwise made an unrealistic or unreasonable proposal.

Written Cost/Price Narrative with support documentation

The written cost/price narrative must provide a detailed and comprehensive description of proposed labor, hours, direct, indirect (when applicable), and other direct costs, estimating techniques used and allocation methods that correlate in sufficient depth with the tasks in the SOW. For expenditure-based solutions, the Proposer must provide cost build up data for labor rates beginning with the unburdened labor rates through application of indirect and profit/fee. The Proposer must not propose labor rates that are derived from blending two or more separate Performers or subcontractor. Proposed indirect rates must be based on the Proposer's **current** Indirect Rate Agreement or Forward Pricing Rate Agreement, if applicable. **Proposers that do not have current negotiated Federal Indirect Rate Agreement (including provisional rates) or Forward Pricing Rate Agreement, MUST propose the flat de minimis indirect rate up to 15%. If using the de minimis indirect rate, ODCs General & Administrative (G&A) must be half of the proposed de minimis rate.** The narrative must indicate how the proposed cost/price is realistic, reasonable, and complete. Cost/price support documentation is required for the Government to properly perform a cost/price analysis of the proposal. The Proposer and each proposed subcontractor must state their business fiscal year.

Supporting Cost/Price Documentation/Information:

Labor. For each government fiscal year, the specific direct labor rates utilized must be identified and include labor hours, labor positions, employee names and escalation rate. The same detailed support data must be furnished for all proposed subcontractor labor. The labor escalation rates for subsequent years (i.e. year two (2) and beyond) may NOT exceed three percent (3%) per year.

Direct labor rates/positions must identify the unburden hourly rate (if proposing a expenditure-based solution) plus projected escalation for each year and the methodology for computing labor rates (i.e. composite) must be shown. **For example:** 3 months of FY27 + 9 months of FY28 divided by 12 = the average labor rate for the award period of performance. The Proposer is advised that projected escalation must be applied to both exempt and non-exempt labor positions.

Indirect Rates. Provide current indirect rates for Fringe, Overhead, Material Handling, General and Administration (G&A), and/or any other indirect costs for all efforts proposed. The Proposer must provide a copy of their current Federally negotiated Indirect Rate Agreement or Forward Pricing Rate Agreement that supports the proposed indirect rates, if applicable. If using the de minimis rate, the Proposer MUST propose a de minimis rate of up to 15%. If using the de minimis indirect rate, ODCs General & Administrative (G&A) must be half of the proposed de minimis rate. When using the de minimis rate, costs must be consistently charged as either direct or indirect costs and may not be double charged or inconsistently charged as both. Proposers are **not** required to provide documentation to justify the de minimis rate.

Subcontractor(s)/Subperformer(s). Subs are considered "other direct costs" and no fee may be applied, however G&A is permitted. For government fiscal each year, the subcontractor burden labor rates shall be used and include labor hours, labor positions, employee names, and escalation rate (not exceeding 3% from year two (2) and beyond). The Offeror must submit a complete breakdown of pricing for each subcontractor proposed as well as (1) nature of services (2)

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timeframe service will be provided, (3) tasks/milestones supported, (4) labor and (5) ODCs (ex: supplies/materials, and travel) and the method by which the Prime Offeror has determined these prices to be fair, reasonable, and realistic. **Signed letters of commitment must clearly identify the subcontractor, service provided, timeframe of service and agreed price and other pertinent conditions (if applicable).** NOTE: There are some terms & conditions from the Prime Agreement that must flow down to any subcontractor/teaming arrangement. See Agreement terms & conditions for details.

Consultants. Consultants are considered “other direct costs” and no fee may be applied, however G&A is permitted. For each government fiscal year, list proposed consultants by name, if known. For each consultant, describe: (1) nature of services (2) timeframe service will be provided, (3) tasks/milestones supported, (4) hourly rate/fee, and (4) and any other related cost (e.g., travel) as well as why the consultant(s) is needed, the method by which the Prime Offeror has determined consultant pricing to be fair, reasonable, and realistic. **Signed letters of commitment must clearly identify the Consultant’s name, service provided, timeframe of service (estimated number of hours) and agreed-to salary/hourly rate and other pertinent conditions (if applicable).**

Materials and Supplies. Materials and Supplies are considered “other direct costs” and no fee may be applied, however G&A is permitted. Provide a detailed listing of materials and supplies, quantity, unit price, and basis of estimate (e.g., vendor quotes, catalog pricing, subcontractor estimates, etc). Competitive historical price information of prior purchases is adequate or current quotes.

Travel. Travel is considered “other direct costs” and no fee may be applied, however G&A is permitted. Provide the number of travelers (no more than 3), purpose, origin (from), destination (to), purpose of travel, and duration, along with a detailed breakdown of pricing.

General Other Direct Costs. No fee may be applied to any general “other direct cost.” List any other direct costs not included in the above categories (e.g., special tooling, computer services, preservation, insurance, etc.). Provide the basis of estimate for each and support documentation (e.g. quote).

Indemnification and Insurance: The Offeror shall indemnify the government through the purchase of liability Insurance. The insurance must include bodily injury/death, no-fault medical expenses, legal defense costs, settlements, product and professional liability, and protocol-driven medical expenses. The policy must identify covered claims (i.e. specific descriptions of what acts, errors, or negligence activate the indemnity obligation) and exclusion limits. The Offeror shall indicate whether the insurance will be covered under the cost of its indirects or separately reimbursed. A copy of policy shall be provided to the government 30 days from award.

Cost per patient:

Accounting System

Although the requirements of FAR 16.301-3(a)(3) do not apply, an expenditure-based (i.e. cost reimbursement) OT agreement that provides for payment based on amounts generated from the awardee’s financial or cost records **require the awardee to have an accounting system capable of identifying the amounts/costs to individual agreements/contracts AND complying with Generally Accepted Accounting Principles (GAAP).** The accounting

system must have effective controls over all project funds, including Federal funds and any required resource share. The system must have complete, accurate, and current records that document the sources of funds and the purpose for which they are disbursed. The accounting system must have procedures for ensuring that the project funds are only for purposes permitted by the terms and conditions of this agreement. **If the Proposer is currently performing under other expenditure-based (i.e., cost reimbursement) Federal procurement contract(s) OR assistance agreement(s)/grant(s), the Proposer is subject to the SAME standards for financial management/accounting systems that apply to those other Federal awards.**

The Proposer MUST describe how the capability of its accounting system meets these requirements.

If the Proposer has any active Federal contracts AND assistance agreements/grants, the cognizant Defense Contract Management Agency (DCMA) and Defense Contract Audit Agency (DCAA), or other Government agency's, name, email address, and telephone number MUST be provided.

Financial Strength

Describe the strategy for future funding and corporate financial stability during the prospective award period. Financial stability, and the ability to address financial stresses, are essential throughout performance under this Agreement.

Disclosure of Same/Similar Work

The Offeror must disclose/confirm whether or not the Offeror has submitted a proposal, or received an award, for the same or similar scope of work under any other transaction agreement, contract, or grant from any federal agency or component thereof as of the date of this submission. If the Offeror has submitted competing proposals or received concurrent awards for a similar or overlapping scope, the Offeror must provide a separate disclosure attachment identifying the agency, award/solicitation number, an explanation of the technical/scope overlap and award status to allow the Government to assess potential duplication or conflict.

Disclosure of previous Small Business Innovation Research (SBIR) work

The Offeror must disclose if the work to be completed within the Offeror's Statement of Work (SOW) derives, extends, or completes a SBIR Phase I or SBIR Phase II. If the work to be completed within the SOW derives, extends, or completes a SBIR Phase I or SBIR Phase II, the Offeror must provide a separate disclosure attachment identifying the agency, award/solicitation number, SBIR status confirmation, project title, abstract, and period of performance/timeline.

4. Proposal Evaluation

4.1 General

Award will be based on the Government's proposal evaluation and subsequent exchanges with the Proposer(s) (if needed). The Government reserves the right to reject the Proposer's proposal, and to award no agreement at all, depending on the quality of the proposal received and the availability of

funds. The proposal must be complete, arrive by the date and time indicated in this RPP and be compliant with all RPP General Instructions.

Government evaluators will NOT assume that the Offeror possesses any capability or products unless it is specified in the proposal and will base its evaluation solely on the information presented in the Offeror's proposal.

The offer shall contain the Offeror's best cost/price and technical and management capability. However, the Government reserves the right to conduct negotiations if later determined by the Agreements Officer to be necessary.

4.2 Proposal Revisions

The Agreements Officer may request or allow proposal revisions to clarify and document understandings reached during negotiations. The Agreements Officer may establish a cut-off date only for receipt of final proposal revisions. The request for final proposal revision may advise the Offeror that the final proposal revision must be in writing and that the Government intends to make award without further revisions.

4.3 Evaluation Factors for Award

The evaluation of the proposal in response to this RPP will be based on a comprehensive review and evaluation of the proposal against all evaluation factors. Ratings consistent with the evaluation criteria will be derived from the Proposer's demonstrated ability to perform the work.

5. Proposal Submission

RPP Questions Due: Offeror shall submit questions in writing using **Attachment J – Proposer question form** no later than: 12:00pm eastern, Friday, 02 Oct 2026.

Proposals Due: 12:00 PM eastern, Friday, 23 Oct 2026.

Questions and proposals must be submitted in writing to Bryan Heckman, DHACA Agreements Specialist via email at bryan.g.heckman.civ@health.mil and Julie Burns at julia.l.burns3.civ@health.mil.

6. Attachments

Attachment A – SOO (REFERENCE ONLY)

Attachment B - CDRL (REFERENCE ONLY)

Attachment C – Data Item Deliverable (DID) (REFERENCE ONLY)

Attachment D1 - FDA Form 1571 (FILL OUT & SUBMIT)

Attachment D2 - FDA Form 1571 Instructions (REFERENCE ONLY)

Attachment E - Draft Agreement Terms & Conditions (RETURN RED-LINED COPY)

Attachment F - Warrants & Representations (FILL OUT & SUBMIT)

Attachment G1 - Cost Sheet Template (for CPFF) (FILL OUT & SUBMIT)

Attachment G2 - Price Sheet Template (for FFP) (FILL OUT & SUBMIT)

Attachment H - SOW Template (TASKS TO BE FILL IN & SUBMIT)

RPP No. HT942726RE020

Prototype development for Battlefield Wound Infection Prevention and Treatment (BWI P&T)
Barrier

Attachment I1 - Technology Readiness Level (TRL) for drugs & biologics (REFERENCE ONLY)

Attachment I2 - Technology Readiness Level (TRL) for diagnostics & devices (REFERENCE ONLY)

Attachment J – Proposer Question Form (FILL OUT & SUBMIT, if applicable)

(end of RPP)