DPA26BZ03-DV012
Engineering Sleep for Cognitive Performance
Frequently Asked Questions (FAQs)

1. If we go the route of using pilot data, is HSR allowed in Phase I?
   A: Human subject research (HSR) in Phase 1 is allowed.

2. The solicitation states that the primary modalities of interest are auditory and/or photic stimulation. Our concept would not rely on either of those modalities. Therefore, before investing significant effort, we wanted to ask whether a noninvasive, closed-loop approach based on modulation of vascular/CSF dynamics during sleep would be considered responsive to the intent of the topic.
   A: Stimulation modalities outside of the listed primary areas may be considered if they meet the requirements outlined in the solicitation and are well justified within the proposal.

3. Please clarify whether **[my system] would be considered responsive to DPA26BZ03-DV012.**
   A: The solicitation states, "The primary modalities of interest for this intra-sleep intervention are auditory stimulation and/or photic stimulation." Stimulation modalities outside of these listed primary areas may be considered if they meet the requirements outlined in the solicitation and are well justified within the proposal.

4. Would [my approach] be more responsive if paired with EEG-guided sleep staging and/or combined with auditory or photic stimulation?
   A: We cannot determine responsiveness of individual ideas prior to review, however, it is likely that the addition of EEG and/or stimulation would strengthen a proposal. Of note, the solicitation states, "Proposals should describe a system that integrates sensors to monitor neurophysiological signals in real-time, with the specific goal of identifying slow-wave sleep (SWS) and other key features of the sleep architecture. Upon detection of these opportune moments, the system should deliver precisely-timed, non-invasive stimuli to augment the brain's intrinsic restorative mechanisms."

5. Has funding been allocated for this topic, and does DARPA anticipate making Direct-to-Phase II awards under this solicitation? If so, approximately how many awards are expected, and are there specific technical maturity or prior research requirements that offerors should demonstrate to be considered for Direct-to-Phase II eligibility?

A: This topic is soliciting both Phase I and Direct to Phase II (DP2) proposals. To be considered for a DP2 award, proposers must demonstrate that the scientific and technical feasibility equivalent to a Phase I effort has already been established by providing detailed evidence of a functional, closed-loop neuromodulation prototype. The number of awards selected depends on the quality of the proposals received.

6. Which cognitive performance outcomes are considered the highest priority for this effort (e.g., vigilance, memory retention, decision-making, reaction time, learning efficiency, or overall operational endurance)?
   A: The solicitation specifies that primary outcome measures for cognitive performance should include "quantifiable improvement (>15%) on validated tasks measuring vigilance, processing speed, and/or executive function (e.g., Psychomotor Vigilance Task (PVT), Digit Symbol Substitution Test (DSST))." All proposals must justify their choice in task selections with references, data and/or theory.

7. What performance metrics are considered most important when evaluating a successful solution (e.g., reduction in sleep requirements, maintenance of cognitive performance, resilience to sleep deprivation, recovery time, or physiological indicators of readiness)?
   A: A successful solution will be evaluated on its ability to produce a quantifiable improvement of over 15% in cognitive performance and show evidence of successful target engagement through physiological mechanisms. These can include "measurable enhancements in sleep architecture (e.g., increased slow-wave activity), or changes in physiological or blood-based biomarkers associated with glymphatic clearance and/or neuroinflammation." All proposals must justify their choice in performance metrics with references, data and/or theory.

8. Is the primary objective to improve the quality of sleep, reduce the quantity of sleep required, accelerate recovery from sleep loss, or develop an integrated capability that addresses all three areas?
   A: The objective is to "develop and demonstrate a wearable, non-invasive, closed-loop system that enhances the restorative functions of sleep" to "measurably improve physiological recovery and sustain cognitive performance under conditions of operational stress, such as sleep restriction." All proposals must justify their strategy to enhance restorative sleep which may include reducing the amount of sleep, accelerating sleep loss recovery or an integrated approach.

9. Are there specific military operational scenarios that are driving this requirement, such as extended-duration missions, special operations, aviation, distributed maritime operations, or other high-tempo environments?
   A: The solicitation does not specify particular military operational scenarios. It states the technology could be transitioned to "programs focused on warfighter performance and resilience" and has applications in pre-deployment conditioning, during operational periods when sleep is limited, and in post-deployment settings.

10. What are the most significant limitations of current sleep optimization, fatigue management, or cognitive enhancement approaches that DARPA is seeking to overcome through this effort?
    A: Proposals need only follow the guidelines outlined in the topic solicitation. The effort seeks to overcome the degradation of essential functions caused by severe sleep restriction, which disrupts the brain's natural restorative processes like glymphatic waste clearance and synaptic plasticity.

11. Are there preferred technical approaches, disciplines, or areas of research that offerors should consider, such as neuroscience, bioengineering, wearable technologies, pharmacological interventions, computational modeling, or closed-loop physiological monitoring systems?
    A: The topic seeks a "wearable, closed-loop system that directly enhances the efficiency and restorative quality of sleep through precisely-timed, non-pharmacological intervention." The primary modalities of interest for intervention are auditory and/or photic stimulation, and proposals that incorporate a synergistic, pre-sleep conditioning modality are also encouraged.

12. Will representative datasets, physiological measurements, operational performance data, or testing environments be available to support development and validation activities?
    A: No. Proposers are responsible for sourcing, generating, and justifying all data and testing materials required to execute their proposed effort.

13. What level of emphasis should be placed on transition feasibility, field deployment considerations, user adoption, and integration into existing military operational workflows during Phase I efforts?
    A: As detailed at https://www.defensesbirsttr.mil/SBIR-STTR/ all proposals will be evaluated in descending order of importance against the following criteria as they relate to the topic proposal:

- **The proposed approach's soundness, technical merit, and innovation and its incremental progress toward topic or subtopic solution.**
- **The proposed principal/key investigators, supporting staff, and consultants' qualifications. Qualifications include not only the ability to perform the R&D but also the ability to commercialize the results.**
- **The potential for commercial (Government or private sector) application and the benefits expected to accrue from this commercialization.**

14. What are the most significant technical, ethical, regulatory, or operational challenges that DARPA anticipates offerors will need to address in order to successfully transition a capability from research to operational use?
    A: Proposers must identify, describe, and justify their own transition strategies, including any technical, ethical, regulatory, or operational challenges applicable to their proposed approach. The solicitation outlines general focus areas, such as Phase II optimization for system robustness, reliability, and user comfort.

15. I am wondering what specific types of neurophysiological signals are of interest. How non-invasive should sensors be? Is there specific stimuli of interest in the closed-loop system? Is there interest in environmental stimuli to augment sleep based on these neurophysiological signals?
    A: The objective is to "develop and demonstrate a wearable, non-invasive, closed-loop system that enhances the restorative functions of sleep" to "measurably improve physiological recovery and sustain cognitive performance under conditions of operational stress, such as sleep restriction." All proposals must justify their strategy to enhance restorative sleep which may include reducing the amount of sleep, accelerating sleep loss recovery or an integrated approach. A successful solution will be evaluated on its ability to produce a quantifiable improvement of over 15% in cognitive performance and show evidence of successful target engagement through physiological mechanisms. These can include "measurable enhancements in sleep architecture (e.g., increased slow-wave activity), or changes in physiological or blood-based biomarkers associated with glymphatic clearance and/or neuroinflammation." All proposals must justify their choice in performance metrics with references, data and/or theory. All types of physiologic signals will be evaluated for their ability to help understand the parameters outlined above. It is possible to look at ways to use environmental stimuli to augment sleep and could be used in this study.

16. Would a proposal be considered responsive if it teams a software/analytics readiness platform (real-time physiological signal ingestion, sleep-stage identification, and closed-loop trigger logic) with a hardware partner providing the wearable sensing and sensory-stimulation delivery -- such that the integrated system meets the closed-loop,

wearable, sensory-stimulation requirement -- or must the responding small business itself be the developer of the stimulation hardware?
A: You may arrange partnerships as you see fit to meet the criteria. Visit DARPAConnect to learn more about teaming, https://learning.theari.us/products/teaming-basics-building-an-effective-team.