

DPA26BZ03-NV012
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.”