Innovative Solutions Opening (ISO)

Restorative and health-Enhancing Sleep Time (REST)

Proactive Health Office (PHO)

Advanced Research Projects Agency for Health

ARPA-H-SOL-26-159

~~June 16, 2026~~

~~June 18, 2026~~

~~June 24, 2026~~

~~July 7, 2026~~

~~July 16, 2026~~

~~August 10, 2026~~

August 11, 2026

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INNOVATIVE SOLUTIONS OPENING (ISO)

Federal Agency: Advanced Research Projects Agency for Health (ARPA-H) Proactive Health Office (PHO)

Program Title: Restorative & health-Enhancing Sleep Time (REST)

Announcement Type: Solicitation

ISO Solicitation Number: ARPA-H-SOL-26-159

Issue Date: June 16, 2026

Proposer's Day: July 13, 2026

Solution Summary Submission Deadline: August 12, 2026 at 12pm ET

Proposal Submission Deadline: October 13, 2026

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Award Instrument: Other Transaction (OT)

PART I: OVERVIEW AND PROGRAM DESCRIPTION

1.1 Program Summary

The Advanced Research Projects Agency for Health (ARPA-H) seeks proposals for the Restorative & health-Enhancing Sleep Time (REST) program, a bold effort to transform how poor sleep is measured and treated by enabling objective, home-based, closed-loop technologies that detect and respond to health-relevant sleep microstructures and respond to them in real time. If successful, REST will establish the technical foundation for a new generation of sleep health technologies that are objective, personalized, and capable of improving long-term health outcomes at scale.

The opportunity is enormous. Approximately 150 million Americans struggle with poor sleep[1], with insomnia as a dominant driver affecting roughly 86 million adults[2], yet existing treatments fail for

[1] Colten, H. R., & Altevogt, B. M. (2006). Committee on sleep medicine and research. *Sleep disorders and sleep deprivation: an unmet public health problem*.
[2] National Institutes of Health. (2021, October 13). *What is insomnia?* NIH MedlinePlus Magazine. https://magazine.medlineplus.gov/multimedia/what-is-insomnia

more than 70% of those patients[3,4]. Poor sleep more than doubles the risk for dementia, depression, hypertension, and diabetes, and contributes to an estimated $400 billion annual economic burden[5]. Despite this scale of impact, every commercially available sleep score today measures only sleep macrostructure (e.g., duration, sleep stages) rather than sleep microstructures—the neurophysiological features of sleep most relevant to restoration and long-term health. The richest measurements remain largely confined to clinical sleep studies, while home-based devices generally lack the fidelity needed for clinically meaningful diagnosis. Current treatment approaches similarly fail to provide individualized, adaptive control of sleep physiology *during* sleep.

ARPA-H believes this gap is bridgeable now. Converging advances in artificial intelligence and machine learning (AI/ML), biosensing wearables, and noninvasive neuromodulation mark this as an inflection point for sleep health. REST seeks bold, interdisciplinary approaches to establish a closed-loop system that defines sleep quality with health as ground truth, measures sleep quality at home with clinical fidelity, and corrects poor sleep in real time throughout the night.

As described below, REST will pursue two Technical Areas of research and development: (1) Measure & Diagnose, to develop in-home systems for measuring and diagnosing poor sleep, including insomnia, using objective physiological signals; and (2) Control & Treat, to develop closed-loop, noninvasive systems for treating poor sleep by adapting interventions to the user's real-time sleep physiology. Proposers may either (1) submit one proposal to one of the two Technical Areas, OR (2) submit one proposal that addresses both Technical Areas as an integrated approach. All proposals must include an emphasis on insomnia. Proposers may also address one or more additional sleep disorders, provided overall REST program objectives are met. A separate, non-solicited program element will support sleep-health modeling, data harmonization, benchmarking, cross-performer integration, and independent verification.

1.2 Problem Statement

Three technical barriers currently prevent progress from sleep measurement to health impact:

First, sleep quality during sleep remains inadequately measured. Current tools emphasize macrostructural features such as duration, timing, regularity, and stage classification. While useful, these measures do not fully capture the fine-grained physiological features of sleep, including microstructural brain activity patterns, that are believed to contribute to memory consolidation, emotion regulation, metabolic regulation, cardiovascular recovery, glymphatic clearance, and other health-relevant processes. As a result, current macrostructural

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[3] He, D., Guo, Z., Mcclure, M. A., Mu, Q., & Jiang, B. (2023). Cognitive-behavioral therapy for insomnia with objective short sleep duration phenotype: A systematic review with meta-analysis. *Sleep Medicine Reviews*, *67*, 101736.

[4] Roth, T., Rosenberg, R., Morin, C. M., Yardley, J., Pinner, K., Perdomo, C., ... & Moline, M. (2022). Impact of lemborexant treatment on insomnia severity: analyses from a 12-month study of adults with insomnia disorder. *Sleep medicine*, *90*, 249-257.

[5] Hafner, M., Stepanek, M., Taylor, J., Troxel, W. M., & Van Stolk, C. (2017). Why sleep matters—the economic costs of insufficient sleep: a cross-country comparative analysis. *Rand health quarterly*, *6*(4), 11.

measurements can describe sleep without reliably determining whether sleep is producing specific restorative benefit or reducing downstream health risk.

Second, clinically informative sleep measures do not translate well to home settings. Polysomnography (PSG) remains the clinical reference standard because it captures rich physiological data, including electroencephalographic (EEG) activity, but it is expensive, burdensome, and poorly suited for repeated or longitudinal home use. Consumer and near-consumer devices are much more scalable, but existing systems do not measure relevant microstructural features and do not support mechanistic diagnosis or personalized treatment selection.

Third, poor sleep cannot yet be adaptively corrected across the night in the home. Existing treatment approaches for insomnia and related sleep problems often rely on generalized treatment strategies, delayed feedback, and trial-and-error adjustment. Although individual noninvasive neuromodulation modalities have shown promise in controlled settings for influencing specific sleep features, no integrated home-based system currently detects relevant physiological features, selects appropriate targets, and adapts intervention in real time across the night to improve sleep quality and related health outcomes.

Together, these barriers leave sleep medicine without a robust path from objective, physiological measurement and diagnostics to personalized, precision home-based intervention. REST is motivated by the hypothesis that sleep can be treated as a controllable biological system: one whose health-relevant features can be identified objectively, measured in the home, and modulated during sleep to improve health.

1.3 Program Vision and Impact

If successful, REST will redefine sleep as an objective, measurable, and controllable biological system that can be optimized to improve health. Rather than treating sleep as a passive state described primarily by duration, stages, or self-reported restfulness, REST seeks to objectively define, measure, and treat sleep based on its biologically restorative qualities. In doing so, the program aims to create the first practical framework for defining sleep quality using downstream health outcomes as the ground truth.

REST is intended to transform three aspects of the current sleep landscape:

- **How "sleep quality" is defined**, replacing simple measures of sleep quantity with objective, predictive metrics of how good sleep is for health;
- **How poor sleep is diagnosed**, replacing clinic-based PSG and subjective self-report with validated, at-home, wearable-based diagnostics for insomnia; and
- **How poor sleep is treated**, replacing trial-and-error with precision control that doubles today's gold-standard insomnia treatment response and remission.

The intended impact of REST is both clinical and societal. Clinically, the program aims to substantially improve outcomes for people with trouble sleeping by increasing insomnia treatment

response from approximately 50% under cognitive behavioral therapy for insomnia (the current gold standard) to at least 90%, and by increasing remission from approximately 30% to at least 80%. More broadly, REST aims to enable reductions in modeled or predicted 10-year risk for major chronic diseases linked to poor sleep, including dementia, depression, cardiovascular disease, and type 2 diabetes, by at least 50%. If achieved, these advances would establish a new foundation for sleep medicine, enable more precise and scalable care, and create a path toward reducing the substantial health and economic burden associated with poor sleep in the United States.

PART II: TECHNICAL AREAS AND REQUIREMENTS

REST is composed of two solicited Technical Areas and a set of non-solicited shared program resources that together support the program's closed-loop approach to sleep health. Rather than treating measurement, diagnosis, and treatment as independent efforts, REST is designed to coordinate these functions across multiple program components so that advances in one part of the program accelerate progress in the others. The solicited Technical Areas are:

1. Technical Area 1 (TA1): Measure & Diagnose – development of validated, in-home systems for objective measurement of sleep-relevant physiology, diagnosis of poor sleep centered on insomnia, and mechanistic classification of poor sleep.
2. Technical Area 2 (TA2): Control & Treat – development of noninvasive, closed-loop systems that adapt intervention to the user's sleep state and physiology in real time to improve sleep quality and treat insomnia.

The shared non-solicited program resources, which ARE NOT solicited under this ISO, are:

3. Foundational Sleep Health Modeling and Discovery – development of shared sleep-health data, models, benchmark targets, and health-anchored definitions of sleep quality.
4. Research Integrator and Independent Verification & Validation (IV&V) – support for program-level coordination, benchmarking, interoperability, and independent technical assessment across performers.

Together, these components are intended to define objective, health-anchored measures of sleep quality; enable clinically meaningful in-home measurement and diagnosis of poor sleep centered on insomnia; and develop personalized, closed-loop approaches to treat poor sleep during the night. The shared program resources are described in Section 2.2 with greater detail for reference so that proposers can understand the broader REST ecosystem and expected interfaces.

By the end of the program, successful TA1 efforts should demonstrate that in-home systems can support real-world screening, diagnosis, and treatment matching for poor sleep. TA2 efforts should demonstrate that noninvasive closed-loop systems can improve insomnia with sufficient usability to support clinical translation. Specific success metrics and phase-by-phase expectations are defined in Part III.

REST is designed to culminate in an integrated closed-loop physical system that brings together sensing, decision, and intervention capabilities developed across the program. That integrated end state may take the form of a single physical device or a coordinated set of devices, provided that

the components operate through an integrated sensing, decision, and control system and collectively achieve the relevant program objectives.

This ISO solicits proposals for Technical Area 1 (TA1) and Technical Area 2 (TA2) only. Proposers may either (1) submit one proposal to one of the two Technical Areas, OR (2) submit one proposal that addresses both Technical Areas as an integrated approach. Proposers may be a prime on only one submission but may be a sub on multiple submissions. Proposals addressing both Technical Areas shall clearly identify the scope, objectives, and evaluation plan for each Technical Area. ARPA-H may select the integrated proposal or may elect to pursue only the TA1 or TA2 component.

2.1 Solicited Components: REST Technical Areas

This ISO solicits proposals in two Technical Areas that address complementary but distinct parts of the program's technical objective. **TA1, Measure & Diagnose**, focuses on developing validated, in-home systems that can objectively measure health-relevant features of sleep, diagnose poor sleep centered on insomnia, and classify mechanistic subtypes using physiological signals. **TA2, Control & Treat**, focuses on developing closed-loop, noninvasive systems that adapt interventions to the user's sleep physiology in real time to improve sleep quality and treat insomnia.

Together, these Technical Areas are intended to move REST from sleep health discovery to real-world implementation by enabling a pathway from objective, in-home measurement and mechanistic diagnostics to precision treatment during the night. Although proposals may address either Technical Area independently or both Technical Areas together, ARPA-H particularly values approaches that clearly articulate how the proposed work will interface with the broader REST ecosystem, including the Foundational Sleep Health Modeling and Discovery and Research Integrator components, and, where relevant, efforts in the other Technical Area.

The following subsections describe the objectives, technical expectations, and proposer guidance for each solicited Technical Area.

2.1.1 Technical Area 1 (TA1): Measure & Diagnose

Objective: Develop validated, consumer-grade in-home systems that measure sleep microstructures with clinical fidelity, classify mechanistic subtypes of insomnia, and link individual sleep profiles to personalized health risks in the domains of cognitive, emotional, cardiovascular, metabolic, and immune health.

Technical Context: PSG is the gold standard for measuring sleep EEG features but is impractical for routine home use, and conventional manual scoring approaches have been largely restricted to sleep stage classification, offering limited insight into underlying sleep microstructures. Consumer wearables and other in-home sensing technologies are more scalable, but existing systems are not trained or validated to measure the sleep microstructures most relevant to health outcomes and insomnia mechanisms. At the same time, foundation models pre-trained on large clinical datasets have shown that clinically rich signals can be translated to lower-burden sensing platforms through transfer learning. REST seeks to apply this principle to sleep by enabling in-home systems that can

measure relevant sleep microstructures, identify mechanistic causes of insomnia, and generate clinically meaningful diagnostic and health-risk information.

Technical Scope and Expectations:

Proposers to TA1 should address all of the following elements:

- **In-home hardware/software development:** Design, build, and iterate on wearable or nearable devices (e.g., wearable EEG, smartwatches, rings, in/under-mattress sensors, WIFI signal analysis) capable of capturing the signals necessary to compute sleep microstructures in the home environment.
- **Clinic-to-home translation:** Develop approaches to translate clinically actionable sleep measurement into low-burden, in-home systems, including but not limited to transfer learning from PSG-based datasets, sensor compression strategies, multimodal modeling, and multi-night measurement approaches. Proposed methods may incorporate additional in-home/wearable data sources beyond EEG and physiology during sleep, such as circadian signals, wearable/continuous biochemical markers, daytime assessments, continuous 24-hour physiology, and environmental context, provided the proposer demonstrates that the approach can achieve fidelity sufficient to support clinically meaningful interpretation on key microstructural features and support objective diagnosis and health-relevant predictions. Proposed methods may also incorporate proposer-generated retrospective or prospective data collection and modeling efforts.
- **Mechanistic insomnia subtype classification:** Develop objective approaches to discover, define, and classify mechanistic subtypes of insomnia (e.g., sleep onset insomnia, excessive light sleep/insufficient slow wave power, excessive awakenings, or other justified subtypes based on deficient restorative microstructures) using physiological, behavioral, circadian, environmental, or other relevant data. Proposers may build on hypothesized subtype categories but should describe how their approach will identify the subtype distinctions and associated microstructural deficiencies most meaningful for health-risk stratification, prevention, and treatment personalization.
- **In-home diagnostic and health prediction capabilities:** Develop in-home systems that translate sleep-related data into objective screening, diagnostic, and individualized health-risk assessment capabilities, validated against appropriate clinical reference standards and outcomes. Proposers should clearly describe the intended use of the proposed system, including whether elements are intended for wellness tracking, health screening, clinical decision support, an/or regulated diagnostic use, and how the proposed development pathway supports that intended use.
- **Human factors and usability:** Conduct human factors engineering and usability testing to demonstrate that the proposed system can be used reliably and acceptably by the intended population in the home setting.
- **Integration with the broader REST ecosystem:** Describe how the proposed system, models, and outputs will interface, as appropriate, with the broader REST program, including use of insights from the Foundational Sleep Health Modeling and Discovery effort; coordination with other performers and the Research Integrator; and participation in common benchmarks, interoperable data structures, and program-level evaluation frameworks. Proposers should also identify any existing datasets, model resources, or other assets they would contribute to the program and describe how those resources could support broader REST objectives, including development of shared sleep health data and

model resources where appropriate. Proposers may also include independent or complementary data generation, curation, harmonization, and modeling activities within their proposed effort.

ARPA-H encourages innovative approaches to in-home sleep measurement and diagnosis and is not prescribing a single sensing, modeling, or translation strategy. Proposed approaches may focus on during-sleep measurements, multi-night measurements, or broader 24-hour characterization of sleep and arousal as interdependent systems, provided the proposer clearly explains how the approach supports the REST objectives and stated program metrics. ARPA-H anticipates that program-level data and model resources will be developed through the broader REST ecosystem to support activities such as pre-training, benchmarking, and cross-performer integration; however, proposers should identify what additional datasets or resources they would require, what datasets or assets they would contribute if available, and how their approach remains technically credible if shared program resources are phased in over time.

For TA1, ARPA-H anticipates that proposers will secure industry cost share that increases as the work matures toward translation and commercialization. Proposers should describe a credible cost share strategy commensurate with the maturity and transition trajectory of the proposed technology, including anticipated source(s) of cost share, when such support is expected to become available (in terms of timing and/or milestones accomplished), and how the proposed cost share approach will support commercialization and long-term sustainability. Specific cost share expectations by program phase are described in PART III: PROGRAM STRUCTURE AND SCHEDULE.

2.1.2 Technical Area 2 (TA2): Control & Treat

Objective: Develop validated, integrated, closed-loop, noninvasive systems that use real-time physiological measurements to personalize and deliver intervention across multiple sleep microstructures during the night to improve sleep quality, treat insomnia, and reduce downstream health risk.

Technical Context: Existing treatments for insomnia are often ineffective, insufficiently personalized, or not designed to directly target the physiological features of sleep most relevant to health. Non-invasive neuromodulation approaches (e.g., haptics, acoustics, transcranial electrical stimulation, focused ultrasound, and related modalities) have demonstrated the ability to modulate specific sleep microstructures in controlled settings. However, no existing system integrates multiple modalities or control strategies, adapts to the individual in real time, targets multiple sleep microstructures across the night, and operates effectively in the home environment. REST seeks to address this gap by enabling closed-loop systems that sense relevant sleep states and microstructural features, personalize intervention to the individual and to within-night variability, and improve clinically meaningful outcomes for insomnia. Such systems may comprise multiple coordinated devices rather than a single unified platform, provided they operate as a coherent, integrated whole. Outputs from the broader REST ecosystem, including foundational modeling and discovery efforts and in-home measurement and diagnostic capabilities, are expected to inform treatment targeting, personalization strategies, and evaluation approaches for TA2 performers.

Technical Scope and Expectations:

Proposers to TA2 should address all of the following elements:

- **Real-time neuromodulation:** Design, build, and iterate systems that use continuous or near-continuous physiological feedback to detect sleep states and relevant microstructural features, and deliver precise, state-dependent or phase-locked intervention during the night using one or more noninvasive modalities. Strong proposals will deliver intervention during sleep, but alternative approaches that are responsive to individual sleep physiology will also be considered. Neuromodulation is not limited to direct energy stimulation of the brain and includes other stimulation modalities that can modulate sleep states and microstructures (e.g., haptics, acoustics, targeted nerve stimulation).
- **Multi-microstructure targeting:** Develop approaches that move beyond single-feature enhancement to coordinate modulation of multiple sleep microstructures relevant to insomnia and downstream health outcomes.
- **Mechanism-informed treatment targeting:** Describe how the proposed approach will identify and respond to mechanisms of poor sleep quality relevant to insomnia, which may include circadian misalignment, altered sleep pressure, dysregulation of arousal systems, stress-related autonomic or hypothalamic-pituitary-adrenal axis activation, age-related changes in sleep physiology, or other justified causal pathways. Proposers should explain how the intervention strategy is matched to the targeted mechanism(s) and why modulation of sleep physiology is expected to improve clinically meaningful outcomes.
- **Candidate intervention portfolio and integration strategy:** Describe a portfolio of at least three candidate interventions relevant to improving sleep quality in insomnia. Candidate interventions may target sleep microstructures, macrostructural sleep features, sleep onset or maintenance, circadian or sleep-drive regulation, autonomic or arousal-related physiology, or other justified mechanisms. Proposers should explain why these candidates are scientifically justified, how they are complementary or otherwise informative as a set, and how the proposed work will compare, down-select, and integrate the most promising elements into a multi-target closed-loop treatment system over the course of the program.
- **Personalization and adaptability to variance:** Develop algorithms and control strategies that adapt intervention parameters to individual physiology, mechanistic subtype, and night-to-night or within-night variability.
- **Integration with diagnosis and measurement:** Describe how treatment decisions will be informed by objective sleep measurements and mechanistic understanding of insomnia, including how the proposed approach will interface with TA1 diagnostic capabilities to identify appropriate candidates for treatment, personalize intervention strategies, and distinguish individuals whose sleep-related symptoms may reflect alternative or co-occurring conditions requiring other evaluation or treatment pathways (e.g., chronic pain, seizure-related disorders, or other non-primary sleep-physiology drivers).
- **Safety and tolerability:** Develop and implement rigorous safety monitoring, risk mitigation, and tolerability assessment plans appropriate for repeated overnight and in-home use.
- **Human subjects research:** Secure Institutional Review Board (IRB) approval for human subjects research evaluating treatment response, remission, and health outcomes in participants with insomnia.
- **Regulatory and commercialization readiness:** Describe plans for device development, product iteration, FDA regulatory strategy, freedom-to-operate analysis, intellectual property strategy, manufacturability, and preparation for later-stage clinical translation,

including engagement with the FDA Center for Devices and Radiological Health (CDRH) beginning in Phase 2.

2.2 Shared Non-Solicited Program Resources

The REST program will provide shared non-solicited program resources that support program-wide discovery, benchmarking, technical integration, and independent evaluation. These resources are not solicited under this ISO and are described for reference so that TA1 and TA2 proposers can understand the broader REST ecosystem and expected interfaces. Shared program resources include: (1) the Foundational Sleep Health Modeling and Discovery Effort, (2) the Research Integrator, and (3) Independent Verification and Validation (IV&V) Effort.

TA1 and TA2 proposers should not assume that all shared program resources will be fully available at the start of performance. Performers will receive rolling access, as appropriate, to shared standards, benchmark targets, common testbed capabilities, and early harmonized data and analytic outputs as those resources are established. More mature shared datasets, models, and evaluation resources are expected to become available progressively thereafter.

Accordingly, proposals for TA1 and/or TA2 should describe how the proposed effort will:

- leverage shared program resources as they become available; and
- remain technically credible and executable as such resources are phased in over time.

ARPA-H expects to provide additional detail regarding the anticipated sequencing, content, and intended use of shared program resources at Proposers' Day and, as appropriate, through subsequent amendments to this ISO.

2.2.1 Foundational Sleep Health Modeling and Discovery

The Foundational Sleep Health Modeling and Discovery component will provide the scientific and analytical foundation for the broader REST ecosystem. REST is building a large-scale sleep health resource by aggregating retrospective PSG and related clinical sleep data from existing research and care settings and linking those records, where available and appropriate, to electronic health records (EHRs), clinical notes, brain imaging files (including magnetic resonance imaging [MRI], computed tomography [CT], and positron emission tomography [PET]), wearable health tracking, laboratory data, and other relevant clinical metadata. PSG-derived data are expected to include both traditional sleep architecture measures and richer physiological features, including spectral EEG measures, spindle and slow oscillation characteristics, sleep stability and microarchitecture metrics, autonomic and cardiopulmonary function measures, and novel composite biomarkers derived from multimodal sleep data. Further specification on the data resource will be presented at the REST Proposer's Day.

Shared resources will be made available on a rolling basis as they are established. At program start, ARPA-H expects the Foundational Sleep Health Modeling and Discovery Effort to have at least 100,000 records fully harmonized and ready for analysis, expanding to up to 450,000 acquired records and initial sleep health models by Month 12 of the REST program, preliminary models and automated harmonization workflows by Month 21, up to 750,000 harmonized records by the end of Phase 2, and up to 1 million harmonized records by the end of Phase 3.

In addition, the REST data team will use modern foundation models and related AI/ML approaches to:

- identify interpretable sleep microstructures causally linked to chronic disease outcomes across multiple health domains;
- derive objective and health-anchored REST metrics of sleep quality;
- evaluate existing sleep treatments against those endpoints; and
- support development of a shared discovery dataset and sleep health model resource over time.

During Phase 1, TA1 and TA2 performers are expected to receive early access to shared schemas, common data elements, and governance conventions; mid-phase access to benchmark targets, at-home measurement guidance, and common testbed capabilities; and later-phase access to harmonized data structures, subtype definitions, and selected early analytic outputs, as appropriate and consistent with data sharing requirements. Outputs from this effort are expected to inform other performers, including, as appropriate, feature selection, benchmark tasks, candidate endpoints, model development, subtype definitions, and health-anchored evaluation approaches.

2.2.2 Research Integrator and Independent Verification and Validation (IV&V)

In parallel with Foundational Sleep Health Modeling and Discovery, ARPA-H anticipates separate Research Integrator and IV&V components to support program-level coordination, technical integration, and independent verification and validation across REST.

The **Research Integrator** will:

- translate relevant outputs from Foundational Sleep Health Modeling and Discovery into forms usable by TA1 and TA2 performers;
- establish and maintain common data elements, benchmarking approaches, and evaluation frameworks;
- assess common testbed needs;
- support interoperability across performer-generated data systems; and
- help de-risk future transition through regulatory planning support and coordination with potential industry partners.

A separate **IV&V** team will provide:

- independent assessment of technical progress;
- integration readiness; and
- data quality assurance and quality control.

Together, the Research Integrator and IV&V components are intended to ensure that REST functions as a coherent ecosystem rather than as a collection of independent efforts.

2.3 Role and Scope of Technical Areas

TA1 and TA2 are complementary components of a broader REST ecosystem that also includes the Foundational Sleep Health Modeling and Discovery Effort and the Research Integrator and IV&V Effort. Realizing the program's objective depends on these components functioning as an integrated whole—through shared standards, common data infrastructure, and aligned objectives—rather than as parallel but independent efforts. The following subsections describe the respective roles of TA1 and TA2 within the REST ecosystem, the coordination expectations that apply to all performers, and the scope and integration requirements for proposals addressing one or both Technical Areas.

2.3.1 Role of TA1 and TA2 Within the REST Ecosystem

Within this broader architecture, TA1 and TA2 are expected to serve complementary but distinct functions.

TA1 performers are expected to develop in-home systems that objectively measure sleep-relevant physiological signals, estimate or detect health-relevant sleep microstructures, support diagnosis of poor sleep centered on insomnia, and classify mechanistic subtypes relevant to prevention and treatment personalization. TA1 outputs are expected to inform broader REST diagnostic benchmarking and, where appropriate, support treatment targeting and personalization in TA2.

TA2 performers are expected to develop noninvasive, closed-loop systems that use real-time physiological measurements to personalize and deliver intervention during the night to improve sleep quality, treat insomnia, and improve health-relevant outcomes. TA2 efforts are expected to draw, where appropriate, on mechanistic understanding, state estimation, and benchmark definitions emerging from TA1 and from the foundational modeling effort, while also generating treatment-response and usability data that may refine broader REST understanding of actionable sleep targets.

2.3.2 Proposal Scope and Ecosystem Integration

Proposals may address one or both Technical Areas; however, ARPA-H particularly values proposals that clearly articulate how the proposed work will integrate with the broader REST ecosystem and, where applicable, interface with efforts in the other Technical Area and the foundational modeling and discovery effort. Proposals addressing both Technical Areas shall clearly identify the scope, objectives, and evaluation plan for each Technical Area. ARPA-H may select the integrated proposal or may elect to pursue only the TA1 or TA2 component.

Proposals addressing a single Technical Area should describe:

- how the proposed effort will interface with complementary REST components;
- what shared resources, benchmark definitions, or integration support the proposer expects to use;
- what outputs the proposer expects to contribute back to the broader REST ecosystem; and
- how the proposed effort remains technically credible as complementary ecosystem resources are phased in over time.

Proposals addressing both Technical Areas should additionally describe:

- the internal integration strategy between diagnostic and treatment components;
- how measurement and mechanistic understanding will inform treatment adaptation;
- how the combined approach will be evaluated relative to both TA1 and TA2 success metrics; and
- how the proposed work will remain interoperable with broader REST program elements, including common benchmarks and Research Integrator activities.

At a minimum, REST anticipates that performers will participate in program-level coordination activities and support reasonable data-sharing, benchmarking, and integration activities consistent with award terms, privacy protections, applicable law, and negotiated intellectual property and data rights. Such activities may include participation in common evaluations, benchmarking exercises, technical interface discussions, integration reviews, program meetings, demonstrations, and site visits.

2.3.3 Out of Scope

The following are examples of activities that are out of scope for this ISO; list is not exhaustive:

For TA1, efforts focused solely on general wellness tracking, sleep hygiene, or conventional sleep scoring (e.g., human-scored sleep stages in 30-second epochs with time-in-stage as the primary output, or actigraphy-derived total sleep time averages across nights as a standalone metric without physiological validation or microstructural context) without a credible path to objective screening, diagnosis, mechanistic characterization or health-relevant prediction.

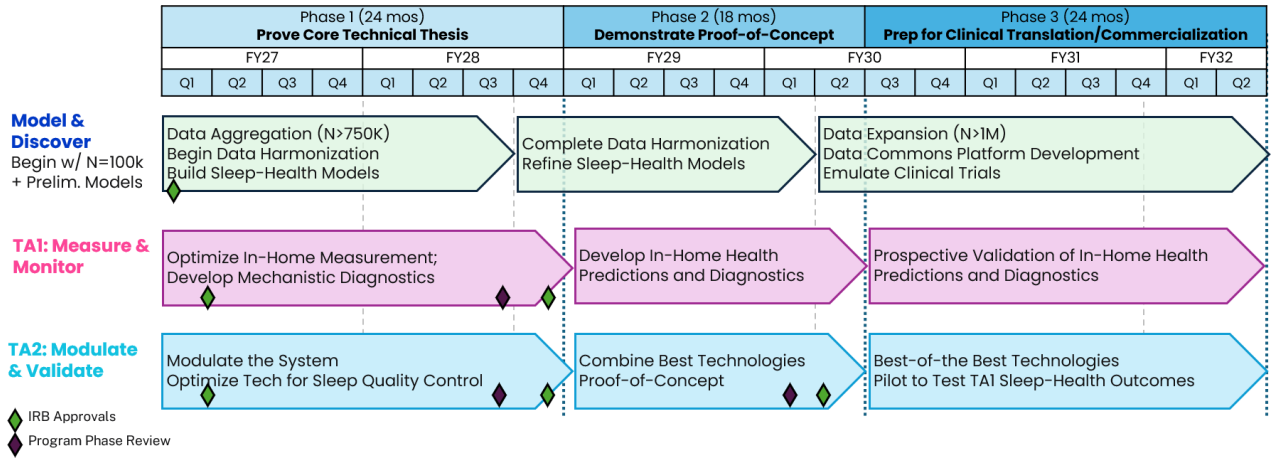
For TA2, efforts focused solely on lifestyle or behavioral interventions, pharmacologic treatment, non-personalized interventions, or interventions that do not credibly use objective physiological measurements to adapt treatment to the user's sleep state or physiology.

For both Technical Areas, efforts focused primarily on standalone infrastructure or other support activities without a direct contribution to the solicited research and development objectives are also out of scope.

PART III: PROGRAM STRUCTURE AND SCHEDULE

3.1 Program Phases

REST is a 66-month (5.5-year) program organized into three phases, as shown in Figure 1:



ARPA-H anticipates a phased program structure with Program Phase Review decision points and may conduct down-selects at phase transitions based on items such as technical progress, integration readiness, and alignment with program objectives.

Phase 1 (Months 1–24): Prove Core Technical Thesis

- TA1: Optimize in-home measurement hardware/software; begin developing mechanistic insomnia diagnostics; demonstrate in-home technology usability.
- TA2: Evaluate a minimum of three candidate intervention approaches, targets, or modalities; characterize their effects on sleep-relevant physiology and sleep quality; and identify the most promising and complementary elements for integration into a multi-target closed-loop treatment system.
- Both TAs: Site visits and demonstrations at approximately Months 12 and 21.
- Program Phase Review; Down-select for TA1 and TA2 performers

Phase 2 (Months 25–42): Demonstrate Proof-of-Concept

- TA1: Develop in-home health predictions and diagnostics; validate in-home technology against PSG.
- TA1: Performers are strongly encouraged to plan for industry cost share of approximately 10% and describe how that cost share would support clinical translation, commercialization readiness, and long-term sustainability of the proposed technology.
- TA2: Combine best technologies; demonstrate proof-of-concept for closed-loop sleep quality control in human subjects.
- Both TAs: Site visit and demonstration at approximately Month 39.
- Program Phase Review; Down-select for TA1 and TA2 performers.

Phase 3 (Months 43–66): Clinical Translation and Commercialization Preparation

- TA1: Prospectively validate in-home health predictions and diagnostics.

- TA1: Performers should plan for industry cost share of approximately 50% in Phase 3 and describe how that cost share supports clinical translation, commercialization readiness, and long-term sustainability of the proposed technology.
- TA2: Complete pilot efficacy trial; plan FDA pivotal trial; submit device to FDA CDRH.
- Both TAs: Site visits and final demonstrations between Months 63-66.

3.2 Program Metrics

The following success metrics define the performance expectations for TA1 and TA2 across the REST program, as applicable to the proposed scope and phase. These metrics are intended to guide evaluation of technical progress, support down-select decisions, and assess whether proposed systems are advancing toward clinically meaningful, usable, and translatable capabilities aligned with REST program objectives.

3.2.1 TA1 Success Metrics

TA1 performers will be expected to achieve the following metrics, as applicable to the proposed scope and phase:

	Phase 1 Prove Tech	Phase 2 Proof-of-Concept	Phase 3 Translation
Metric	24 mos	18 mos	24 mos
Objective Insomnia Diagnostics (AUC re: insomnia diagnosis)	≥ 0.80	≥ 0.90	n/a
Poor Sleep Classification (specificity/sensitivity)	Subtypes set	≥ 75%	≥ 95%
Feature-Level Fidelity to PSG (Pearson's correlation)	≥ 0.75	≥ 0.80	≥ 0.85
Feature-Level Agreement with PSG (intraclass correlation)	≥ 0.70	≥ 0.75	≥ 0.80
Hardware/Software Usability (% above 68 on System Usability Scale)	≥ 80%	≥ 0.90	n/a
Secure Industry Cost Share (% costs shared)[+]	n/a	10%	50%

[+]Cost share is an approximate target.

TA1 is intended to address a central barrier in sleep health: clinically meaningful measurement of poor sleep cannot currently be performed where most people sleep. Accordingly, TA1 success will be evaluated based on the ability of the proposed in-home system to move beyond conventional consumer sleep tracking and demonstrate clinically meaningful capability for objective insomnia diagnosis, poor-sleep classification, mechanistic characterization, and health-relevant prediction in home settings.

In particular, TA1 performers are expected to show that low-burden in-home sensing approaches can preserve the information necessary to support clinically meaningful interpretation of sleep, even when using fewer or different sensors than full polysomnography. Success is therefore not defined only by the ability to approximate isolated features, but by the ability to reproduce, with clinically meaningful fidelity and agreement, the PSG-derived features, composite measures, and/or model-relevant outputs necessary to support diagnosis, mechanistic characterization, and health prediction, as appropriate to the proposed approach.

The table above reflects the expectation that TA1 systems should improve progressively across the program in several linked areas. First, performers should demonstrate increasingly strong objective diagnostic performance for insomnia. Second, performers should demonstrate increasingly accurate classification of poor sleep and, where applicable, mechanistic subtypes relevant to prevention, treatment personalization, and risk stratification. Third, performers should demonstrate that in-home systems can reproduce key sleep-related features with fidelity relative to polysomnography and show meaningful agreement with appropriate clinical reference measurements. Fourth, performers should demonstrate that these outputs are not merely descriptive, but sufficiently informative to support clinically relevant PSG-based inferences and downstream health prediction. Fifth, performers should demonstrate that the proposed hardware and software can be used reliably and acceptably by the intended population in the home environment.

3.2.2 TA2 Success Metrics

TA2 performers will be expected to achieve the following metrics, as applicable to the proposed scope and phase:

	Phase 1 Prove Tech	Phase 2 Proof-of-Concept	Phase 3 Translation
Metric	24 mos	18 mos	24 mos
Insomnia Response (% with Insomnia Severity Index reduction ≥ 7)	n/a	≥ 75%	≥ 90%
Insomnia Remission (% with Insomnia Severity Index total score ≤ 7)	n/a	≥ 55%	≥ 80%
Sleep Quality-Health Response[+] (% with clinically significant improvement)	≥ 65%	≥ 75%	≥ 85%
Chronic Disease Risk Reduction (% with reduction in 10-year health risks)	n/a	≥ 33%	≥ 50%
Hardware/Software Usability (% above 68 on System Usability Scale)	n/a	≥ 70%	≥ 80%

[+]Target set at month 12.

TA2 is intended to address a central barrier in sleep health: poor sleep cannot currently be adaptively corrected across the night in the home using objective physiological measurements. Accordingly, TA2 success will be evaluated based on the ability of the proposed closed-loop system to improve insomnia symptoms, achieve remission, produce clinically meaningful improvement in health-anchored sleep quality, reduce downstream chronic disease risk, and demonstrate acceptable hardware and software usability in the target population.

In particular, TA2 performers are expected to show that noninvasive, closed-loop intervention strategies can use real-time physiological information to personalize treatment to the individual and to within-night variability. Success is therefore not defined only by the ability to modulate a single sleep feature in isolation, but by the ability to identify, compare, and ultimately integrate candidate interventions that can produce meaningful improvements across the five outcome areas reflected in the table above.

The table above reflects the expectation that TA2 systems should improve progressively across the program in five linked areas. First, performers should demonstrate increasingly strong insomnia response, reflected in clinically meaningful symptom improvement. Second, performers should demonstrate increasingly strong insomnia remission, reflecting the ability of the proposed system

to move beyond partial benefit and achieve absence of clinically significant symptoms in a substantial proportion of users. Third, performers should demonstrate increasingly meaningful sleep quality-health response, showing that the intervention improves health-anchored sleep quality rather than only isolated sleep features or subjective impressions. Fourth, performers should demonstrate measurable chronic disease risk reduction, consistent with the broader REST objective of improving long-term health trajectories associated with poor sleep. Fifth, performers should demonstrate that the proposed hardware and software are sufficiently usable for repeated overnight use in the home by the intended population.

3.3 Key Program Milestones

Below provides an overview of key program milestones. Note that proposers are encouraged to propose additional milestones, and in general, ARPA-H uses a quarterly milestone payment schedule for awarded performers.

Timeline	**Program Milestone**
Month 3	TA1/TA2: IRB approvals in place
Month 12	TA1/TA2: Human subjects enrollment underway TA1: Submit short list of potential transition partners
Month 21	TA1: In-home technology demonstrated usable, identify proposed transition partner, provide documentation of intent to partner, and submit revised Phase 2 statement of work (SOW) TA2: Optimal neuromodulation technologies identified
Month 22	First Program Phase Review
Month 39	TA1: In-home diagnostics validated; diagnostics linked to health outcomes TA2: Treatments demonstrated usable and impactful~~; device submitted to FDA CDRH~~
Month 40	Second Program Phase Review
Month 43	TA2: Device(s) submitted to FDA CDRH
Month 66	TA1: Health predictions prospectively validated TA2: Pilot trial complete; FDA pivotal trial planned

PART IV: PROPOSAL REQUIREMENTS

4.1 Eligibility

ARPA-H is primarily interested in proposals from commercial performers, academic institutions, and non-profit organizations. Federally Funded Research and Development Centers (FFRDCs) and government entities, including federal employees, are **not permitted** to respond to this ISO as a prime or sub-performer. ~~See the FFRDC and Government Entity Participation policy for limited exceptions and waiver procedures.~~

ARPA-H must prioritize awards to entities that will conduct the funded work in the United States. Non-domestic performers are encouraged to collaborate with a domestic entity. ARPA-H will not

make awards to entities organized under the laws of a covered foreign country per 42 U.S.C. 290c(n)(1)(D).

System for Award Management (SAM): An active SAM.gov registration and Unique Entity Identifier (UEI) is required to receive an award. NOTE: SAM actions may take more than 14 business days to process; at times it may take up to 90 days. SAM is independent of ARPA-H and thus ARPA-H representatives have no influence over processing timeframes.

4.2 Award Instruments

ARPA-H may award Other Transaction (OTs) agreements resulting from proposals submitted in response to this ISO.

4.3 Solution Summaries (Pre-Proposal Submissions)

ARPA-H requires submission of a Solution Summary prior to submission of a Proposal. Solution Summaries allow ARPA-H to assess the viability of proposed concepts prior to ~~Full~~ Proposals.

Submission of a Solution Summary is mandatory. ARPA-H will review submitted Solution Summaries and either *encourage* submission of a Proposal or *discourage* submission of a Proposal. Note that a Solution Summary may be evaluated to be of merit but discouraged from submitting a Proposal. Although a Proposal may be submitted regardless of ARPA-H's determination, potential proposers are advised to give the government's determination significant weight when deciding whether to invest time and resources in the development of a Proposal. Additional feedback may not be provided.

Solution Summary Format (Attachment A):

Use of Attachment A is required.

- Maximum 6 pages for single TA, 8 pages if submitting to both (excluding cover page and references)
- Must include:
  1. Technical Area(s) addressed;
  2. Technical approach overview;
  3. Team qualifications and relevant prior work;
  4. Key risks and proposed mitigations;
  5. Rough order of magnitude (ROM) budget
  6. For TA1 proposers only, a preliminary cost share strategy, including anticipated source(s) of cost share, when such support is expected to become available, and how the proposed cost share approach supports transition and commercialization
- Submit to: https://solutions.arpa-h.gov/submit-summary
- Solution Summary Deadline: August 12, 2026 at 12pm ET

4.4 ~~Full~~ Proposal Requirements

As noted above, following Solution Summary evaluation, proposers will be either encouraged to, or discouraged from, submitting a Proposal. Although a Proposal may be submitted regardless of ARPA-H's determination, potential proposers are advised to give the government's determination significant weight when deciding whether to invest time and resources in the development of a Proposal.

The Proposal process will include submission of the following documents:

1. **Volume I — Technical Proposal (maximum 9 pages)**
   - Revised Solution Summary if requested (maximum 6 pages)
   - Supporting Evidence (maximum 3 pages)
     - Summarize any data, analyses, or other evidence supporting the feasibility, plausibility, safety, or technical credibility of the proposed approach
     - May include, as applicable, pilot or proof-of-concept data, relevant findings from peer-reviewed publications, existing datasets, existing models, prototype results, prior demonstrations, or other technical assets the team would bring to the program.
     - Proposers may cite published work generated by the team or by others, provided they clearly explain how that evidence supports the proposed REST effort.
2. **Volume II — Cost Proposal (no page limit)**
   - Cost by year and phase, broken out by TA as applicable, with supporting narrative and documentation
   - Cost realism narrative for labor rates, indirect rates, and materials/equipment
   - Milestone-based payment structure proposal, with payable milestones tied to technical deliverables
   - Note: If the cost proposal differs materially from the Solution Summary, ARPA-H may re-evaluate the project's suitability for award.

3. **Volume III — Human Subjects Research (HSR) / Animal Subjects Research (ASR) (maximum 2 pages)**
   - Summarize the proposed research methodology, sample size justification, participant recruitment and enrollment strategy, safety monitoring approach, adverse event management, and anticipated IRB path and timing.

4. **Volume IV — Team Qualifications (maximum 5 pages for each key personnel)**

   - Include biosketches for key personnel.
5. **Volume V — Transition & Commercialization Plan (maximum 3 pages)**
   - Describe the transition and commercialization strategy, including intended end users, value proposition, anticipated pathway, and key commercialization milestones.
   - Include intellectual property strategy and anticipated partner approach.
   - Summarize the regulatory strategy, including FDA engagement plans as applicable.

- For TA1 proposers, provide the anticipated cost share strategy, including expected source(s), timing, and role in supporting transition and commercialization
- For TA2 proposers, describe the clinical translation and regulatory preparation strategy, including preparation for later-stage validation and pivotal study planning.

All Proposals will be evaluated in accordance with Part V Evaluation Criteria and Selection. Only those selected from the Proposal phase will be invited to provide an in-person Pitch.

4.4.1 Pitch Requirements

Only those selected from the Proposal phase will be invited provide an in-person Pitch.

~~The oral presentation is the primary component of the Full Proposal.~~ Invited proposers must deliver a 45-minute pitch session, consisting of 15 minutes for oral presentation and 30 minutes for question-and-answer discussion for proposals addressing one Technical Area. For Proposals addressing both Technical Areas, invited proposers must deliver a 60-minute pitch session, consisting of 25 minutes of oral presentation followed by 35 minutes of question-and-answer discussion. Unless otherwise specified by ARPA-H, the slide deck must be limited to a maximum of 15 slides for proposals addressing one Technical Area and 20 slides for proposals addressing both Technical Areas.

ARPA-H may use the Q&A portion of the session to probe technical depth, program realism, integration strategy, team readiness, commercialization planning, and other issues relevant to evaluation.

More information and guidance will be provided to those selected to provide an in-person Pitch.

4.5 ~~Full~~ Proposal Submission Instructions

More information and guidance on submitting a ~~Full~~ Proposal will be provided at a later date.

PART V: EVALUATION CRITERIA AND SELECTION

5.1 Solution Summary Evaluation

ARPA-H will review and respond to each conforming Solution Summary submission. Solution Summaries will be reviewed for the purpose of providing feedback regarding whether ARPA-H is interested in the Solution Summary concept. At a minimum, the government's response will indicate whether submission of a Proposal is *encouraged* or *discouraged*. Although a Proposal may be submitted regardless of the feedback provided, potential proposers are advised to give the government's decision significant weight when determining whether to invest time and resources in the development of a Proposal.

Non-conforming Solution Summaries and Proposal submissions may be removed from consideration. If a submission is determined to be non-conforming and will not advance for further consideration, the proposer will be notified via email. No additional feedback will be provided.

5.2 Proposal Evaluation

All conforming Proposals will be evaluated by qualified Government Evaluators through ARPA-H's Scientific Review Process. ARPA-H will evaluate Proposals based on consideration of scientific and technical merit, feasibility, and innovation of the solution as well as Proposer's capabilities and relevant experience. ARPA-H will use the criteria to determine which Proposals will be invited to provide an in-person Pitch. Only those invited will be eligible to present a Pitch. Proposals are evaluated independently; they are not ranked or compared against each other during evaluation. Proposals may be deemed to be of merit and not invited to Pitch.

An award will be made to a proposer(s) whose Proposal and Pitch are determined to be the most advantageous to the Government, consistent with instructions and evaluation criteria, and based on availability of funding.

ARPA-H reserves the right to incorporate into the resulting agreement(s) any aspect of the successful Proposal(s), including the Solution Summary and Pitch, that is evaluated, relied upon, or otherwise considered in ARPA-H's selection decision.

5.2 Selection

After Pitch evaluations, ARPA-H will select proposers for negotiations. Proposers will be notified via email after their Pitch evaluation if they are selected or not selected for negotiations. Notifications will not occur until after all Pitches have been fully reviewed and evaluated. Selection for negotiations does not constitute an award. ARPA-H is not required to make any award under this ISO and reserves the right to select all, some, or none of the proposals received. ARPA-H may select proposals for full or partial funding. As such, a proposer's Pitch may be evaluated to be of merit but not selected for negotiations. Those not selected for negotiations will be notified via email.

PART VI: GENERAL INFORMATION

6.1 Research Security

ARPA-H will conduct a Research Security Review (RSR) of all ~~Full~~ Proposals selected for negotiations. Teams selected for awards will be required to submit required documents provided with ~~Full~~ Proposal instructions.

6.2 Intellectual Property

ARPA-H will negotiate intellectual property and data rights as part of award negotiations. Proposers are encouraged to describe their IP strategy in their Commercialization Plan. ARPA-H intends to negotiate terms that enable both government use and commercial transition of program outputs.

6.3 Publication and Dissemination

ARPA-H expects research results to be broadly publishable consistent with the fundamental research principles, subject to pre-publication review by ARPA-H. Performers are prohibited from using ARPA-H logos without written authorization from COMPASS.

6.4 Proposers' Day

ARPA-H intends to host a hybrid Proposers' Day event on July 13, 2026. Attendance is encouraged but not required. Details will be posted to https://arpa-h.gov/explore-funding/programs/rest and https://sam.gov. Presentations from Proposers' Day will be made publicly available following the event.

6.5 Questions and Answers

Questions regarding this ISO must be submitted via the Solutions site Ask-A-Question (select REST in the dropdown). The Solutions site can be found at: solutions.arpa-h.gov/ask-a-question

Questions and responses of general applicability will be posted publicly. Please check posted answers before submitting a question; duplicate answers will not be provided. The following types of questions will not be answered:

- Which Technical Area is most appropriate for a team to submit to
- Whether a team's idea fits within the REST program scope
- Preferences of teaming arrangements
- ARPA-H's general thoughts on a topic

6.6 Disclaimers

This ISO does not constitute a commitment by the U.S. Government to make an award, nor does it commit ARPA-H to pay any costs incurred in the preparation or submission of a Solution Summary or ~~Full~~ Proposal. ARPA-H reserves the right to cancel this ISO at any time.