### **DARPA** Overview

Dr. Jim Gimlett Deputy Director Defense Sciences Office (DSO)

**RESTORE** Proposers Day

March 14, 2025



Distribution Statement "A" (Approved for Public Release, Distribution Unlimited)





ATACMS: Army Tactical Missile System LRASM: Long Range Anti-Ship Missile



### DARPA technical offices





### DSO Thrust Areas





#### SENSING, MEASURING, & AFFECTING

Pushing to fundamental limits for orders-ofmagnitude improvement in capabilities



#### MATH, COMPUTATION, & PROCESSING

Enabling quantum, and reimagining classical, computing for enhanced efficiency and new capabilities



#### MATERIALS, MANUFACTURING, & STRUCTURES

Breaking the tension between performance and efficiency for critical parts, energetics, superconductors, and propulsion



#### COMPLEX, DYNAMIC, & INTELLIGENT SYSTEMS

Foundations of intelligence for human-AI ecosystems and to enable warfighter capabilities

### **PROPELLING SCIENCE FROM BENCH TO BATTLEFIELD**





### Advanced Research Concepts (ARC)

- New process to quickly capture and rigorously evaluate many ideas
- Focus is on answering high risk/high-reward "what if?" questions



### **DARPA Innovation Fellowship**

- 2-year Fellowship for early career scientists
- Build a long-term pool of diverse talent that can focus on national security

## SCIENTISTS WANTED

to push the limits of technology; decent wages, difficult journey, long months of scientific analysis, constant risk of failure, outcome uncertain; honor and recognition in case of success.



fellowship@darpa.mil



## D A R P A CONNECT DISCOVER - COLLABORATE - CONTRIBUTE

DARPAConnect is designed to broaden DARPA's reach and stimulate **growth and collaboration** between DARPA, businesses, and academia.



#### DARPAConnect@darpa.mil



### Evolutionary vs. Revolutionary R&D



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#### 9 October 1903

"The flying machine which will really fly might be evolved by the combined and continuous efforts of mathematicians and mechanicians in from one million to ten million years"

- The New York Times



"We started assembly today." - Orville Wright's Diary



www.darpa.mil

### www.darpa.mil/dso

Sign up for DSO news updates to receive notification on new opportunities

### Reengineering Enabling Sleep Transitions in Operationally Restrictive Environments (RESTORE)

Greg Witkop, M.D. Program Manager, Defense Sciences Office

**RESTORE** Proposers Day

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"The vast majority of scientific understanding advances incrementally, with new projects building upon the results of previous studies or testing long-standing hypotheses and theories." (NSB-07-32)



BRAIN: Brain Research Through Advancing Innovative Neurotechnologies MD: Maryland NIH: National Institutes of Health NSB: National Science Board



"Less frequently, scientific understanding advances dramatically, through the application of radically different approaches or interpretations that result in the creation of new paradigms or new scientific fields." (NSB-07-32)

DARPA 2014 Systems-Based Neurotechnology for Emerging Therapies (SUBNETS) program





Kirkby, Luongo, Lee et al. (2018)



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- The New York Times







**RESTORE** goal



Belenky, et al. 2003

RESTORE will transform our ability to maintain performance / health on less sleep and more rapidly recover from sleep loss



# In the event of a BAA posting, if there is any discrepancy between what is presented today and the BAA, the BAA takes precedence



### Opening Comments

- The Proposers Day briefing is intended to provide an orientation to the RESTORE Broad Area Announcement and is solely for information purposes
- The solicitation supersedes anything presented or said by DARPA at the Proposers Day
- Examples in this briefing (e.g., technologies, use cases) are chosen for ease of illustration only and do not constitute endorsement of any particular approach
- Interested performers are expected to be able to articulate a clear and compelling vision for their technology, proposed course of research, and transition potential
- Teaming is important! Today is a great opportunity for networking
- We need your help to make this program a success!



### Teaming is important

- To fully address the BAA, you may need to team with other entities
- Each team should submit a unified proposal under a single prime
- This BAA is open to educational institutions, government labs, and/or private companies
- Foreign entities may join a team or submit as the PI
- Even if you are a member of a team, you may still join any number of other proposal teams or form your own and submit a proposal as PI
  - Note: no person or organization may be a performer on more than one *awarded* TA effort, either as a prime or subcontractor
- You must find your collaborators on your own, but today is a great opportunity for networking!
- Note that the cost volume for each subcontract must be at the same level of details as for the prime



"Sleep may be the most important biological factor that determines Service member health and combat readiness" - DoD Report to the Congressional Armed Services Committees (2021)

Sleep rebalances the brain and body

- Release hormones to promote recovery
- Consolidate neuroplastic brain changes
- Improves cognitive functioning
- Supports adaptation to stress and trauma

Sleep optimizes performance and health

- Alertness and reaction time
- Judgement and decision making
- Learning and Memory
- Emotional Regulation
- Psychological Resilience





Military operational tempo disrupts sleep creating warfighter health and readiness vulnerabilities

#### **Risks of Disrupted Sleep Biomarkers of Disrupted Sleep** Health Neuroimaging 70% of service members (vs. 28% of civilians) are clinically sleep **Disrupted Architectures** Normal Decreased activity in the deprived (<6 hours of sleep per night) Good et al. (2020) areas responsible for cognitive function and *Pre-deployment* deprivation: increased activity in fear/ • 1.8x increased risk of post-deployment TBI Luxton et al. (2011) panic areas • 2.8x increased risk of *post-deployment* suicide Wang et al. (2018) • 3.1x increased risk of *post-deployment* PTSD Wang et al. (2018) **Cognitive Testing** Readiness 7 Day Restricted Sleep Baseline Recovery < 3 hours of sleep common Lapses **15.0** h TIB in combat (Weeks, 2010) Identification and accuracy 6h TIB Attention 8 9 Hr decreases 2.2x 5.0 4.7.80 Increases hallucinations 8h TIB • 5.m 8 · 3.90 (no target) by 1.6x (WRAIR, 2023) 4 6 8 10 12 14 2 Days of sleep restriction Banks & Dinges (2007) T1 T2 B 1 2 1 4 5 6 7 R1 R2 R0

Increased errors in health and readiness testing (attention and focus)

WRAIR: Walter Reid Army Institute of Research

Disrupted sleep damages the brain causing cognitive impairment and, potentially, mental illness

BL: baseline

mPFC: medial prefrontal cortex PTSD: post-traumatic stress disorder

TBI: traumatic brain injury TIB: time in bed

(Belenky et al., 2003)

Direct relationship between disrupted sleep

architectures and cognitive impairment

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### Current solutions – wakefulness at the expense of restorative sleep

#### Pharmacology

#### <u>Caffeine</u>



#### <u>Amphetamines</u>

Decrease brain network connections while increasing risk of abuse and dependence (Manconi et al., 2023)

Side effects: Anxiety, dizziness, headaches



Caffeine disrupts restorative sleep architectures (Grimaldi et al., 2020)



Neurostimulation

#### Acoustic stimulation of slow wave sleep increases cognitive performance by 5% (25% improvement needed for significant behavioral response)



Blue light increased connectivity between brain areas for cognitive control (L PFC) and attention (L PHG) resulting in fewer lapses)

#### Wakefulness approaches disrupt complete restorative sleep necessary to repair the brain

L PFC: left prefontal cortex ms: milliseconds L PHG: left parahippocampal gyrus PVT: psychomotor vigilance task mg: milligram RT: reaction time WRAIR: Walter Reid Army Institute of Research



### Sleep medicine interventions focus on extending duration of sleep



NIH recommendations

- Sleep "hygiene" for 7-9 hours of sleep
- Cognitive Behavioral Therapy-Insomnia (CBT-I)
- Pharmacology most not approved for military use due to side effects and risks of abuse
- Impractical for warfighters in theater



Acoustic stimulation can increase onset of slow wave sleep ("deep sleep") (Lustenberger et al., 2022)

#### These approaches assume routine 7-9 hours of sleep is possible

Hz: hertz NIH: National Institutes for Health SWA: slow wave activity PSG: polysomnography

stim: stimulation µV: microvolt

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### Restorative Sleep: Evolution's daily repair and optimization of brain and body function

#### **Restorative Sleep**

Sleep Architectures	Micro-architectures
Non-REM Sleep Stage 1	Theta waves (4-8 Hz)
Non-REM Sleep Stage 2	Sleep spindles (12-14 Hz)
Non-REM Sleep Stage 3	Delta/slow waves (1-4 Hz) Slow oscillations (0.5-1 Hz)
REM sleep	Theta waves (4-8 Hz)





#### **RESTORE – Orchestrating precision control of whole brain sleep architectures**



Hypothesis: Orchestrating whole brain sleep architectures will repair damaged brain networks causing cognitive impairment



Macro-architecture: The structural organization of sleep, including rapid eye movement (REM) and non-rapid eye movement (NREM)

**Micro-architecture:** The electrical signature of NREM sleep, characterized by distinct brainwave patterns such as slow waves, K-complexes, and sleep spindles



### Out of Scope Activities

- Interventions to improve wakefulness/cognitive performance independent of improving sleep
- Study protocols that do not include human subjects, such as studies only including simulations, biophysical models, and animal models.
- Any proposal not clearly stating the specific strategies, techniques, and justifications for how proposed methods will successfully execute both of the program's key technical objectives.
- Proposals that develop general sleep interventions intended to support individuals in getting a full 7-8 hours of sleep
  without increasing the restorative effect of specific sleep micro-architectures or without the ability to increase restorative
  effects under conditions of restricted sleep.
- Proposals that focus extensively on developing novel neuroimaging, neurostimulation, or sleep intervention technologies (e.g., new pharmacological agents) without a clear justification for their necessity compared to existing techniques.
- Proposals that focus extensively on developing novel cognitive-behavioral tasks, clinical scales, or other such assessments, without a clear justification for their necessity compared to existing techniques (e.g., psychomotor vigilance, task switching, digit symbol substitution).
- Interventions that cannot be tested and demonstrated within the program's stated timelines, such that those that would require the need for safety studies prior to testing or those that are not able to receive FDA approval for clinical testing within program timelines.
- Proposals that rely on interventions that have not previously been shown capable of modulating sleep micro-architectures.
- Proposals that involve children and/or adolescents under 18 years old.



### **RESTORE** Proposals

### Successful proposals will succinctly and explicitly explain:

- The fundamental hypothesis to be tested, including the underlying assumptions and expected outcomes
- How results will change neuroscience understanding; specifically, how they will advance our knowledge of sleep and its relationship to cognitive performance, if the hypothesis is supported
- Evidence, data, projections, calculations, or theoretical explanations of how the proposed methods are capable of meeting the program's metrics. Proposals lacking such justifications are unlikely to be selected for award
- The potential implications of the proposed research for future work relating to sleep and cognitive function
- The theoretical neurobiological basis for the proposed interventions, including the underlying mechanisms
- Research design, including specific power analysis, to evaluate the effectiveness of the interventions
- Biomarkers that demonstrate a link between changes in brain activity and improvement in cognitive performance, and how these biomarkers will be measured and analyzed
- Specific plans, including cost and time estimates, to address the three key technical challenges outlined in the program description

#### Successful proposals will not:

- Simply reiterate the justifications or background information provided in the BAA
- Require the development of new drugs or pharmacologic interventions
- Rely on existing pharmacologic interventions known to disrupt sleep, pose a risk of dependency or misuse, or increase performance risk if the individual is awakened prior to drug clearance



RESTORE will demonstrate potential to reduce cognitive impairment by controlling restorative sleep

#### Key Technical Objective 1:

Develop a multimodal system that enables the precision control and optimization of sleep macroand micro-architectures

### Key Technical Objective 2:

Evaluate changes in sleep macro- and micro-architectures and their mediating effects on pre- and postintervention brain activity, sleep and cognitive performance





### How does restorative sleep impact the brain?



Restorative sleep repairs the brain daily to maintain cognitive performance

CSF: cerebral spinal fluid REM: rapid eye movement sleep Hz: hertz SWA: slow wave activity hdEEG: high density electroencephalogram NREM: non-REM sleep





Hz: hertz PGO: Ponto-Geniculo-Occipital REM: rapid eye movement tACS: transcranial alternating current stimulation



### Evidence that orchestrating whole brain sleep architectures is possible



Hz: hertzTES: transcranial electrical stimulations: secondstDCS: slow oscillatory transcranial direct current stimulationμV: microvoltTFR: time-frequency representation



Evidence that synergistic neuromodulation improves neurophysiology and cognitive performance

Visual and auditory neuromodulation using scalable technologies



## Hybrid stimulation increased brain activity more than single method stimulation



### Synergistic technologies improved physiology and cognitive impairment

Phase 2 Clinical Trial, FDA Breakthrough Technology (Chan et al., 2022)



RESTORE Hypothesis: Orchestrating whole brain sleep architectures will overcome cognitive deficits of sleep deprivation



20+ years - No solution

RESTORE: Improved biomarker measurement of disrupted sleep

#### Cognitive testing of multiple performance domains





number is even-odd or >5



Neuroimaging of biomarkers to increase mechanistic understanding





RESTORE: Gold standard sleep restriction and intervention study



- Induce and measure cognitive impairment and brain dysfunction
- Conduct a sham-controlled intervention trial
- Evaluate prevention of cognitive impairment and brain dysfunction in sleep restricted state

24-month MVP establishes basis for potential solutions to 20-year military challenge



MVP: Demonstrate 1) control of sleep architectures , 2) a statistically significant neurophysiological measure of brain restoration, and 3) improved cognitive outcomes				
Military Cognitive Performance Domains	Test	Metric (3-hour sleep restriction)		
Attention* and Alertness* (sentry)	Psychomotor Vigilance Task Reaction time and lapses	25% improvement in cognitive performance		
Monitoring* and Response Inhibition* (friendly fire/hostage rescue)	Task Switching Accuracy and response time	25% improvement in cognitive performance		
Processing Speed* (navigation)	Digital Symbol Substitution Test Accuracy and response time	25% improvement in cognitive performance		



\*Military performance experts' consensus of critical components of cognitive performance (Albertelle, 2023)







### General guidance

- RESTORE aims to transform broad areas of the DoD Human Domain through applied research
- Achieving the RESTORE program goals will require tightly-integrated, multidisciplinary teams that can address both of the key R&D challenges
- RESTORE is comprised of two key Technical Objectives (TOs)
  - Each proposal should address **both** TOs
    - DARPA will consider proposals that do not address both technical objectives as non-responsive and will not evaluate them
  - Proposers should strive to provide a clear understanding of the cost, risk, and organizational expertise to be used within each proposed effort
  - Pay attention to "must" and "should" language in the BAA
  - Submitting a proposal abstract is highly recommended

#### Focus on multidisciplinary capabilities and teaming



- Please submit any questions to RESTORE@darpa.mil
- Answers to the questions will be provided later and posted to <a href="https://sam.gov/">https://sam.gov/</a>
- Select presentation materials will be made available after clearing public release



www.darpa.mil



"Sleep may be the most important biological factor that determines Service member health and combat readiness" DoD Report to the Congressional Armed Services Committees (2021)

Yet...

69-72% of soldiers are chronically sleep restricted (<6hrs), compared to 28% of civilians (Good, et al. 2020)





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Yet...

69-72% of soldiers are chronically sleep restricted (<6hrs), compared to 28% of civilians

<u>Mental Health</u>: < 6 hours sleep/night pre-deployment:

• Increases post-deployment TBI 1.8X, alcohol abuse 1.9X, suicide 3.8X, PTSD 4.7X (Good, et al. 2020)

Performance: < 3 hours of sleep common in combat (Weeks, 2010)

- Identification and accuracy decreases 220%
- Increases false fires (no target) by 164% (WRAIR)







- Seven Days of Restricted Sleep: Effects on Vigilance
- 69-72% of Soldiers are chronically sleep restricted (< 6 hours per night) vs. 28% of civilians (Good, et al. 2020)
- </=3 hours sleep is common for combat operations & training, and 20-hour day-cycles are common for many military duties (Weeks et al., 2010)
- After 3 days of limited sleep, soldiers' ability to identify/shoot the enemy 220% and 164% shot at things that did not exist (WRAIR)
- During deployment, > 50% of accidents are caused by sleep and circadian disruptions (WRAIR)
  - < 6 hours sleep/night pre-deployment leads to increased postdeployment TBI (1.8x), alcohol abuse (1.9x), suicide (3.8x), and PTSD (4.7x) (Good et al., 2020; Luxton et al. 2011; U.S. Department of Defense, 2021)

## Hypothesis: Sleep and circadian rhythm disruption is causal rather than a secondary comorbid effect of psychopathology



### **Current Treatments**

<ul> <li>Cognitive Behavioral Therapy for Insomnia (Muench et al., 2022)</li> <li>70-80% respond, ~50% reduction in symptom severity, long-term sustained effect</li> <li>4-8 weeks for effectiveness</li> <li>Requires optimal sleep practices and settings not feasible for many military demands</li> </ul>	Throughts Throughts	at	<ul> <li>Sleep promoting Rx medications (e.g., Ambien)</li> <li>Improve sleep onset, wakenings, and duration</li> <li>Side effects: drowsiness, dizziness, headaches</li> <li>Risks: abuse, dependence, sleep disturbance</li> <li>Wake-promoting Rx medications (e.g., Provigil)</li> <li>Treat excessive sleepiness caused by SCDs</li> <li>Side effects include anxiety, dizziness, headaches</li> <li>Risks: abuse, dependence, sleep disturbance</li> </ul>
<ul> <li>Stimulants</li> <li>Immediate effectiveness</li> <li>Can cause sleep disruptions</li> <li>Rx stimulants (e.g., Provigil) prohibited for most military uses due to risk of abuse</li> <li>Do not treat sleep disorders</li> </ul>	Mitig	ate	<ul> <li>Tactical napping:</li> <li>Improve alertness and fatigue</li> <li>Best results require dark and quiet location not available in many military deployment conditions</li> <li>Unknown ability to target restorative mechanisms</li> </ul>





NREM EEG: "slow" aka 1-4 Hz (delta) waves, K-complexes (high-amplitude delta waves) or sleep spindles (waxing-and-waving 11–16 Hz transient oscillation





### Recent technological advances create potential for closed loop, whole brain systems





Military performance psychologists' consensus of critical components of cognitive performance: Attention, Alertness, Response Inhibition, Processing Speed, Monitoring (Albertelle, 2023)





Digital Symbol Substitution Test					
1 2 3 4 5 6 7 8 9 - 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1					
Sample Items 2 1 3 7 2 4 8 2 1 3 2 1 4 2 3 5 2 3 1 4 1 - 7 1 5 L 5 4 1 2 1 4 2 3 5 2 3 1 4					
56314154276357285463					
Match symbols to numbers according to given key					

Attention and Alertness Reaction Time & Lapses <u>Sentry</u>

MVP: minimum viable program PTSD: post-traumatic stress disorder TBI: traumatic brain injury DoD: Department of Defense ms: millisecond Response Inhibition and Monitoring Reaction Time & Accuracy Shoot / No Shoot <u>Hostage Rescue & Friendly Fire</u>

Processing Speed Reaction Time & Accuracy <u>Navigation</u>

### Broad Agency Announcement (BAA) Reengineering Enabling Sleep Transitions in Operationally Restrictive Environments (RESTORE) Doing Business with DARPA

#### Lydia Richards Contracting / Grants / Agreements Officer DARPA Contracts Management Office

February 4, 2025





- Will be posted on SAM.gov and grants.gov websites
- This is a 24 months, single-phase program
- Multiple Awards are anticipated.
- Please pay attention to due dates in BAA and special instructions outlined in the new BAA Model format

### Potential Award Instrument Types:

- Procurement contracts
- Cooperative Agreements
- o Other Transaction (OT) for Prototype
- o OT for Research
- DARPA expects solutions to be either fundamental OR nonfundamental research

NOTE: If there is any discrepancy between what is presented today and the BAA, the BAA takes precedence.



- Abstracts are strongly encouraged, but not required.
  - Attachment A: Abstract Summary Slide (Required if submitting an Abstract)
  - Attachment B: Abstract Instructions and Template (Required if submitting an Abstract)
- The Program Manager will respond to each Abstract with feedback either <u>encouraging or discouraging</u> a full proposal submission.
- Proposers may submit a full proposal even if the Abstract is discouraged.



### **Full Proposal Tips**

- Read the BAA carefully Non-conforming proposals may be rejected without review.
- Please ensure review of eligibility and statutory requirements when requesting an Other Transaction
- A full proposal must include 2 volumes
  - Procurement contracts OR OT-Ps:
  - 1. Technical Approach & Management (Volume I)
    - Proposal Summary Slide Template = Attachment C = REQUIRED
    - Proposal Instructions and Volume I Template = Attachment D = **REQUIRED**
  - 2. Cost Proposal (Volume II) = <u>No page limit</u>
    - Proposal Instructions and Volume II Template = Attachment E = REQUIRED
    - MS Excel DARPA Standard Cost Proposal Spreadsheet = Attachment F = REQUIRED
  - □ Cooperative Agreements or OT-Rs:
  - 1. Technical Approach & Management (Volume I): Attachments C and D are REQUIRED
  - 2. Cost Proposal (Volume II): Attachment E is REQUIRED and SF424 (R&R) Budget form through Grants.gov



• All responsible sources capable of satisfying the Government's needs may submit a proposal that shall be considered by DARPA.

#### • FFRDCs, UARCs & National Labs: subject to limitations

 Federally Funded Research and Development Centers (FFRDCs), University Affiliated Research Centers (UARCs), and Government entities interested in participating in this opportunity or proposing to this BAA must first contact the point of contact listed in the Overview Information section prior to the Abstract due date to discuss eligibility.

### • Organizational Conflicts of Interest:

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



- No common Statement of Work Proposals are evaluated on individual merit and relevance as it relates to the stated research goals/objectives rather than against each other.
- Proposals are evaluated for strengths and weaknesses relative to the criteria published in the BAA, listed in *descending order of importance*:

### Refer to BAA for details regarding proposal evaluation



- Government reserves the right to select for award all, some (partial selection), or none of the proposals received.
- Multiple awards are possible. The amount of resources made available under this BAA will depend on the quality of the proposals received and the availability of funds.
- <u>Contract negotiation timelines depend on each institution/organization's</u> <u>responsiveness to the proposal requirements in the BAA.</u>
- The contracting office will contact the selected performers and begin the contracting process.

### Refer to BAA for details regarding proposal evaluation



**Once it is published, r**ead the BAA **over and over again** and follow all instructions carefully.

A conforming proposal addresses **all aspects** of the BAA

Pay attention to "must", "should", "shall", and "all" in the BAA

DO NOT try to shoehorn ongoing, but not applicable, work into a BAA response

**DO NOT** submit a rewritten USDA, NIH or NSF abstract

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

DO NOT submit an irrelevant or incomplete abstract in the hope we'll fund it anyway

A proposal abstract is **STRONGLY RECOMMENDED**, but not required

**Register for an account at the BAA Portal** (<u>https://baa.darpa.mil</u>)

### Human Subjects Research at DARPA

Component Office for Human Research Protections (COHRP)



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The term "human subject" can be applied to research efforts that meet <u>EITHER</u> of the following criteria: A living individual about whom an investigator (whether professional or student) conducting research:

- Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
- Obtains, uses, studies, analyzes, or generates identifiable private information, personally identifiable information, or identifiable biospecimens.

Human Subjects Research involves:

 Activities that include both a systematic investigation designed to develop or contribute to generalizable knowledge and involve a living individual about whom an investigator conducting research obtains information or biospecimens through intervention or interaction with the individual, or identifiable private information, or biospecimens.

## Any DARPA-funded research which involves humans as defined on this page MUST be considered HSR.



# All DARPA human subjects research protocols must go through two reviews





### HSR approval Process

- Principal Investigator submits protocol to local IRB for review and approval
- HSR package is then submitted for DoD headquarter review and approval
  - Includes local IRB approval letter
  - Federal Wide Assurance (of institution performing research)
  - Informed Consent Document \*\*\*Make sure informed consent document includes statement that the research is being funded by DoD and thus the DoD has access to the data\*\*\*
  - Recruiting Materials
  - Biosketches/CVs
  - Training Certifications
- DoD review authority, reviews the entire package
  - May go back to PI with comments/recommendations/changes
- Once DoD HRPO approval is obtained, HSR research can begin
- Note that protected populations (i.e. military, pregnant women, etc.) have special regulations that need to be followed. This includes such things as command level approval for recruitment of subjects (active duty military)

Note – DoD HRPO review and approval can take anywhere from 3-6 months. Do not delay in starting this process!



### Helpful Hints/FAQs

- If possible, submit an IRB approval letter and/or a Draft HSR Protocol with proposal. Especially, in cases where humans are involved and you don't know that the work is really HSR. Having an IRB already look at it will help you and DARPA in moving forward faster.
- If you do not have an internal IRB, you have one of three options
  - Hire a commercial IRB
  - Work with the Contracting Agent to determine if they have an internal IRB that could assist
  - If work involves collaboration with other performers, considering using their IRB
- If you have a contract involving subcontractors who are conducting HSR; they will also need to obtain HSR approval. Any performer including subcontractors must receive HSR approval through the local IRB and the DoD HRPO office, before start of their research.
- If you make changes to the statement of work, they also need to be approved. If the changes are to the HSR portion of the work, the revisions will have to go through the local IRB for review, as well as DoD HRPO office for approval and concurrence.



For questions pertaining to HSR in this program, please contact the DARPA PM/SETA team and they will route your questions to the DARPA COHRP