

Broad Agency Announcement

## Strengthening Resilient Emotions and Nimble Cognition Through Engineering Neuroplasticity (STRENGTHEN) Defense Sciences Office

HR001123S0016

November 15, 2022

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#### BAA Attachments:

- Attachment A: ABSTRACT SUMMARY SLIDE TEMPLATE
- Attachment B: ABSTRACT TEMPLATE
- Attachment C: PROPOSAL SUMMARY SLIDE TEMPLATE
- Attachment D: PROPOSAL TEMPLATE VOLUME 1: TECHNICAL & MANAGEMENT
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- Attachment G: PROPOSAL TEMPLATE VOLUME 3: ADMINISTRATIVE & NATIONAL POLICY REQUIREMENTS

## **PART I: OVERVIEW INFORMATION**

- Federal Agency Name: Defense Advanced Research Projects Agency (DARPA), Defense Sciences Office (DSO)
- **Funding Opportunity Title:** Strengthening Resilient Emotions and Nimble Cognition Through Engineering Neuroplasticity (STRENGTHEN)
- Announcement Type: Initial Announcement
- Funding Opportunity Number: HR001123S0016
- Catalog of Federal Domestic Assistance (CFDA) Number(s): 12.910 Research and Technology Development
- Dates (All times listed herein are Eastern Time.)
  - Posting Date: November 15, 2022
  - o Proposers Day: November 18, 2022. See Section VIII.A.
  - o Abstract Due Date: November 30, 2022, 4:00 p.m.
  - o FAQ Submission Deadline: January 13, 2023, 4:00 p.m. See Section VIII.B.
  - o Full Proposal Due Date: January 23, 2023, 4:00 p.m.
- Anticipated Individual Awards: DARPA Anticipates one or more awards.
- **Types of Instruments that May be Awarded:** Procurement contracts, cooperative agreements or Other Transaction for Prototype agreements. Award instruments will be limited to procurement contracts and Other Transactions for Proposers whose proposed solution includes Controlled Unclassified Information (CUI).
- Agency contacts
  - o Technical POC: Gregory Witkop, Program Manager, DARPA/DSO
  - BAA Email: <u>STRENGTHEN@darpa.mil</u>
  - BAA Mailing Address:

DARPA/DSO ATTN: HR001123S0016 675 North Randolph Street Arlington, VA 22203-2114

- DARPA/DSO Opportunities Website: <u>http://www.darpa.mil/work-with-us/opportunities</u>
- Teaming Information: See Section VIII.C for information on teaming opportunities.
- **Frequently Asked Questions (FAQ):** FAQs for this solicitation may be viewed on the DARPA/DSO Opportunities Website. See Section VIII.B for further information.
- Security: STRENGTHEN is an UNCLASSIFIED program. If proposers would like to work with Controlled Unclassified Information (CUI) please specify so in the abstract and proposal and refer to Section IV.B.4.

## PART II: FULL TEXT OF ANNOUNCEMENT

#### I. Funding Opportunity Description

This Broad Agency Announcement (BAA) constitutes a public notice of a competitive funding opportunity as described in Federal Acquisition Regulation (FAR) 6.102(d)(2) and 35.016 as well as 2 C.F.R. § 200.203. Any resultant negotiations and/or awards will follow all laws and regulations applicable to the specific award instrument(s) available under this BAA, e.g., FAR 15.4 for procurement contracts.

## A. Introduction

The Defense Sciences Office (DSO) at the Defense Advanced Research Projects Agency (DARPA) is soliciting innovative research proposals in the area of neurobehavioral protective factors and wellbeing to prevent and mitigate the effects of traumatic stress leading to suicidality and behavioral health disorders in warfighters. Proposed research should investigate innovative approaches that enable revolutionary advances in science, devices, or systems. Research that primarily results in evolutionary improvements to the existing state of practice is specifically excluded.

#### **B.** Background

Developing effective approaches to prevent suicide is a top priority within the U.S. Department of Defense. STRENGTHEN aims to build on recent advances in neuroscience and clinical practice to increase wellbeing, and prevent and mitigate the effects of traumatic stress leading to behavioral health disorders and suicidality in warfighter and civilian populations. STRENGTHEN will accomplish this goal through enhancing the behavioral health protective factors of cognitive flexibility (CF) and emotion regulation (ER).

Proposers must assume human subject testing will be considered Human Subjects Research (HSR) and plan for the Institutional Review Board (IRB) and secondary Human Research Protection Office (HRPO) reviews that are necessary for Government-sponsored HSR in the proposed cost and schedule. No HSR data collection can begin prior to HRPO approval.

Current efforts to prevent and mitigate the impact of traumatic stress on warfighters rely on the nosological approach of the Diagnostic and Statistical Manual of Mental Disorders (DSM-5). While useful clinically, the DSM-5 focuses on classification of symptoms into categorical behavioral health diagnoses, which can be limiting because it focuses on symptomatic effects rather than causes of disease. The underlying biopsychosocial mechanisms associated with behavioral health disorders, however, are transdiagnostic,<sup>1</sup> complex, interactive, and poorly understood.<sup>1</sup> While suicidality is not a DSM-5 diagnosis, current efforts to treat and prevent it are similarly limited by a focus on subjective descriptions of risk rather than empirical causal

<sup>&</sup>lt;sup>1</sup> Dalgleish T, Black M, Johnston D, Bevan A. Transdiagnostic approaches to mental health problems: Current status and future directions. Journal of consulting and clinical psychology. 2020;88(3):179. https://doi.org/10.1037/ccp0000482

mechanisms of suicidality.<sup>2</sup> After 50-years of research into risk factors, accurate identification of suicidality is only slightly greater than chance.<sup>3</sup> Additionally, although behavioral health disorders are associated with a higher incidence of suicide, the majority of service members who die by suicide do not have a history of a behavioral health disorder.<sup>4</sup>

The STRENGTHEN program aims to overcome the limitations of focusing on descriptions of individual disease effects and suicide risk factors by adopting a transdiagnostic approach that addresses the mechanisms (i.e., predictors or causes) of mental health and wellbeing (see for example the dimensional frameworks proposed by the Hierarchical Taxonomy of Psychopathology [HiTOP] and the Research Domain Construct [RDoC]).<sup>5</sup> Specifically, STRENGTHEN will optimize the brain networks essential for CF and ER, establishing dose response, time-to-onset, and duration-of-effect curves to quantify the impact of change in CF and ER on validated measures of suicidality, behavioral health, and wellbeing.

A recent longitudinal neuroimaging study of victims of childhood sexual and non-sexual physical abuse revealed the effect of functional CF and ER networks in protecting against depression.<sup>6</sup> In terms of overcoming diagnostic heterogeneity and targeting specific networks with technology-based interventions, recent work has demonstrated neuroimaging biotypes of depression that could not be distinguished with current subjective diagnostic methods yet could predict responsiveness to technology interventions.<sup>7</sup> While no one has attempted to engineer changes in CF and ER brain network activation patterns to build protective factors against the impacts of traumatic stress, recent clinical work has shown numerous noninvasive techniques designed to decrease subjective symptoms of mental illness have resulted in neuroplastic changes in brain networks.<sup>8</sup> Methods include: cognitive, such as Cognitive Behavioral Therapy/CBT and meditation;<sup>9</sup> chemical, such as psilocybin, ketamine, or Methylenedioxy

<sup>&</sup>lt;sup>2</sup> Millner AJ, Robinaugh DJ, Nock MK. Advancing the understanding of suicide: The need for formal theory and rigorous descriptive research. Trends in cognitive sciences. 2020;24(9):704-16. https://doi.org/10.1016/j.tics.2020.06.007

<sup>&</sup>lt;sup>3</sup> Franklin JC, Ribeiro JD, Fox KR, Bentley KH, Kleiman EM, Huang X, Musacchio KM, Jaroszewski AC, Chang BP, Nock MK. Risk factors for suicidal thoughts and behaviors: A meta-analysis of 50 years of research. Psychological bulletin. 2017;143(2):187. <u>https://doi.org/10.1037/bul0000084</u>

<sup>&</sup>lt;sup>4</sup> Pruitt LD, Smolenski DJ, Bush NE, Tucker J, Issa F, Hoyt TV, Reger MA. Suicide in the military: understanding rates and risk factors across the United States' armed forces. Military medicine. 2019;184(Supplement\_1):432-7. https://doi.org/10.1093/milmed/usy296

<sup>&</sup>lt;sup>5</sup> Michelini G, Palumbo IM, DeYoung CG, Latzman RD, Kotov R. Linking RDoC and HiTOP: A new interface for advancing psychiatric nosology and neuroscience. Clinical psychology review. 2021;86:102025. https://doi.org/10.1016/j.cpr.2021.102025

<sup>&</sup>lt;sup>6</sup> Rodman AM, Jenness JL, Weissman DG, Pine DS, McLaughlin KA. Neurobiological markers of resilience to depression following childhood maltreatment: The role of neural circuits supporting the cognitive control of emotion. Biological psychiatry. 2019;86(6):464-73. <u>https://doi.org/10.1016/j.biopsych.2019.04.033</u>

<sup>&</sup>lt;sup>7</sup> Drysdale AT, Grosenick L, Downar J, Dunlop K, Mansouri F, Meng Y, Fetcho RN, Zebley B, Oathes DJ, Etkin A, Schatzberg AF. Resting-state connectivity biomarkers define neurophysiological subtypes of depression. Nature medicine. 2017;23(1):28-38. <u>https://doi.org/10.1038/nm.4246</u>

<sup>&</sup>lt;sup>8</sup> Cash RF, Weigand A, Zalesky A, Siddiqi SH, Downar J, Fitzgerald PB, Fox MD. Using brain imaging to improve spatial targeting of transcranial magnetic stimulation for depression. Biological Psychiatry. 2021;90(10):689-700. https://doi.org/10.1016/j.biopsych.2020.05.033

<sup>&</sup>lt;sup>9</sup> Laukkonen RE, Slagter HA. From many to (n) one: Meditation and the plasticity of the predictive mind. Neuroscience & Biobehavioral Reviews. 2021;128:199-217. <u>https://doi.org/10.1016/j.neubiorev.2021.06.021</u>

methamphetamine/MDMA;<sup>10</sup> physical exercise;<sup>11</sup> electric, such as Electroconvulsive Therapy/ECT;<sup>12</sup> magnetic, such as TMS;<sup>13</sup> and ultrasound, such as Transcranial Ultrasound Therapy/TUS.<sup>14</sup> For convenience, this BAA will summarize cognitive, chemical, exercise, electric, magnetic, and ultrasonic techniques as C2E2MU.

## C. Program Description/Scope

For the purposes of defining terminology for this solicitation and the STRENGTHEN program, the following definitions apply:

- *C2E2MU*: cognitive, chemical, electrical, exercise, magnetic, and ultrasonic
- *Cognitive flexibility:* Mental ability to switch between thinking about two different concepts according to the context of a situation.
- *Emotion regulation:* Conscious or nonconscious strategy to start, stop, or otherwise modulate the trajectory of an emotion.
- *External intervention*: A method of inducing adaptive neuroplastic changes by means of agents external to the human body. Examples of external agents could include, but are not limited to, magnetic, electric, ultrasound, or chemical interventions.
- *Internal intervention*: A method of inducing adaptive neuroplastic changes through goal directed activities. Examples of goal directed activities could include, but are not limited to Cogntive Behavioral Therapy (CBT), Dialectical Behavioral Therapy (DBT), meditation, cognitive training, or physical exercise.
- *Hybrid intervention*: An intervention strategy that integrates at least one internal intervention with at least one external intervention such that the combined interventions have complementary effects for optimizing the brain circuits responsible for CF and ER.

STRENGTHEN will strive to optimize the protective mechanisms of CF and ER through two goals:

- Development of individualized brain network models of CF and ER.
- Design of hybrid interventions to induce adaptive neuroplastic change in the functional connectivity and/or structure of CF and ER brain networks to optimize an individual's CF and ER.

<sup>&</sup>lt;sup>10</sup>Carhart-Harris RL, Friston K. REBUS and the anarchic brain: toward a unified model of the brain action of psychedelics. Pharmacological reviews. 2019;71(3):316-44. <u>https://doi.org/10.1124/pr.118.017160</u>

<sup>&</sup>lt;sup>11</sup> Shors TJ, Chang HY, Millon EM. MAP Training My Brain<sup>TM</sup>: meditation plus aerobic exercise lessens trauma of sexual violence more than either activity alone. Frontiers in neuroscience. 2018;12:211. https://doi:10.3389/fnins.2018.00211

<sup>&</sup>lt;sup>12</sup> Sackeim HA. Modern electroconvulsive therapy: vastly improved yet greatly underused. JAMA psychiatry. 2017;74(8):779-80. <u>https://doi.org/10.1001/jamapsychiatry.2017.1670</u>

<sup>&</sup>lt;sup>13</sup> Williams LM, Coman JT, Stetz PC, Walker NC, Kozel FA, George MS, Yoon J, Hack LM, Madore MR, Lim KO, Philip NS. Identifying response and predictive biomarkers for Transcranial magnetic stimulation outcomes: protocol and rationale for a mechanistic study of functional neuroimaging and behavioral biomarkers in veterans with Pharmacoresistant depression. BMC psychiatry. 2021;(1):1-7. <u>https://doi.org/10.1186/s12888-020-03030-z</u> <sup>14</sup> Sanguinetti JL, Hameroff S, Smith EE, Sato T, Daft CM, Tyler WJ, Allen JJ. Transcranial focused ultrasound to the right prefrontal cortex improves mood and alters functional connectivity in humans. Frontiers in human

neuroscience. 2020;14:52. https://doi.org/10.3389/fnhum.2020.00052

To this end, STRENGTHEN will conduct longitudinal studies to optimize an individual's CF and ER in low risk, at risk, and high risk for suicide populations through the following four key processes:

- Identification of individual-specific CF and ER brain networks using validated psychometric testing and neuroimaging (e.g., resting state or task-activated functional connectivity).
- Development of individualized neurobehavioral models linking brain network activity and connectivity with CF and ER behavioral outcomes (e.g., error rates and response).
- Designing of hybrid interventions targeting individualized neurobehavioral models to improve CF and ER behavioral outcomes via neuroplastic changes to brain networks that support CF/ER.
- Establishment of dose response, time to onset, and effect duration curves linking changes in CF and ER behavioral outcomes to Impact Assessments of validated measures of wellbeing (e.g., Emotional Scale Questionnaire), clinical symptoms (e.g., Clinician Administered Post Traumatic Stress Disorder for DSM-5 Scale, Beck Depression Index), and suicidality (e.g., Self-Injurious Thoughts and Behaviors Interview) in low risk, at risk, and high risk for suicide populations.

Over the course of the program STRENGTHEN performers will develop hybrid interventions to enhance CF and ER and prevent adverse outcomes for three populations:

- *Low risk*: cohort of a generally healthy community sample that includes people who may experience noticeable depression or anxiety, but do not have current or a recent history of mental illness diagnosis and treatment, i.e., a general "healthy" community population.
- *At Risk*: cohort that includes people who have current or recent history of outpatient treatment for depression, PTSD, anxiety, or other mental illness that puts them at risk of suicide.
- *High Risk*: cohort that includes people who are currently receiving treatment for suicidality, i.e., individuals at high risk of attempting and/or dying by suicide.

Specifically, out of scope activities include:

- Any proposal not clearly stating the specific strategies, techniques, and justifications for how proposed methods will successfully execute all four key processes to meet metrics and maximize Impact Assessments.
- Proposals that develop general brain network models or general-purpose network analytics without a clear strategy for how such work will support CF and ER modeling and analytics.
- Proposals that focus extensively on developing novel neuroimaging sensor technologies without a clear justification for their necessity compared to existing techniques (e.g., functional magnetic resonance imaging [fMRI], magnetic resonance imaging [MRI], electroencephalogram [EEG], magnetoencephalography [MEG], functional near-infrared spectroscopy [NIRS]).
- Proposals that focus extensively on developing novel cognitive-behavioral tasks, clinical scales, or other such assessments of wellbeing without a clear justification for their necessity compared to existing techniques (e.g., intra-extra dimensional set shift, variations of Eriksen flanker, cognitive reappraisal, emotional Stroop, etc.).

- New 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.
- Modeling approaches that focus on general population level trends and which cannot be adapted to the individual.
- Proposals that focus on a single internal or external intervention and that do not develop some kind of hybrid approach.
- Proposals that rely on interventions that have not previously been shown to induce neuroplastic changes in brain networks.
- Proposals that involve children and/or adolescents under 18 years old.

## **D.** Program Structure

STRENGTHEN is a 42-month research and development effort comprising three phases and encompassing two technical areas (TAs). Phase 1 will be 18 months, Phase 2 and Phase 3 will be 12 months in duration:



## **Technical Areas (TAs)**

**TA1: Neuro-Mechanistic Models:** Performers will develop individualized brain network models of CF and ER.

**TA2: Neuroplastic Interventions:** Performers will design hybrid interventions to induce neuroplastic change in the functional connectivity and/or structure of CF and ER brain networks to optimize an individual's CF and ER.

TA1 models are important for meeting TA2 intervention goals; therefore, proposers must propose to both TAs across all Phases. Proposals that address only one TA may be considered non-conforming and removed from consideration. Section I.E describes the TAs in more detail.

#### Phase structure

DARPA will use a Phased Acquisition Approach for STRENGTHEN. Proposer should provide fully detailed technical and cost proposals for the Phase 1 Base effort, and Phase 2 Option.

Phase 2 selection decisions are at the sole discretion of the Government and will be based on performance against the program goals and metrics (see Section I.E); overall progress towards the STRENGTHEN program objectives such as transformative effects on impact assessments of wellbeing, clinical improvement, and decrease in suicidality; each performer's individual programmatic objectives; and the availability of funds. The Government retains the right to award all, some, one, none, or portions of the proposed Phase 2 options. to support promising further technology developments.

Proposers should provide a draft statement of work (SOW) and rough order of magnitude (ROM) cost for Phase 3. The Phase 3 draft SOW and ROM is for budgetary purposes only and will not be evaluated. DARPA intends to issue proposal instructions to Phase 2 performers whose Phase 2 option has been exercised requesting revised technical and cost proposals for Phase 3 near the end of Phase 2. Phase 3 proposals will be evaluated using the evaluation criteria in Section V.A of this BAAParticipation in any given phase does not guarantee funding in a subsequent phase.

Throughout all three phases, performers should establish the neuroscience basis for future DoD and NIH clinical trials of precision medicine approaches to increase well-being, prevent suicidal ideation, and decrease adverse behavioral health outcomes in three risk populations: low risk, at risk, and high risk for suicide. Initial proposals should clearly identify which specific cohorts they will be working with for low-risk, at-risk, and high-risk populations across all phases, to include the notional Phase 3.

**Phase 1 (Base):** Performers will identify and evaluate initial hybrid intervention strategies for <u>all</u> populations by developing initial models, testing initial interventions, and measuring pre-post effects of those interventions on CF and ER. Phase 1 Human Subjects Research (HSR) must include at least 1 of the three populations (low risk, at risk, or high risk).

**Phase 2 (Option):** Performers will evaluate hybrid intervention enhancements by refining Phase 1 models, testing additional interventions, and measuring the pre-to-post effect of those interventions on CF and ER. Phase 2 HSR must continue to study the chosen Phase 1 population and add at least one additional risk population.

**Phase 3 (Notional):** If awarded, Phase 3 performers will optimize methods by further refining the mechanistic models, refining hybrid interventions, and continuing to assess efficacy by measuring pre-to-post effects of those interventions on CF and ER. If awarded, Phase 3 will include the final population so that all three risk populations will be included in Phase 3 HSR. Final details will be provided in the proposal instructions issued near the end of Phase 2.

Proposers may choose to include more than one of the three risk populations in Phase 1 and more than two of the risk populations in Phase 2 provided they can maintain high study quality and do so within the program's schedule. The proposed SOW and costs must clearly articulate which tasks and costs are associated with which population. Phase 2 should be proposed with separate options for each population. Proposal costs and SOWs should align with standard mental health proof-of-concept studies rather than large scale treatment effect studies.

Given the variability of appropriate C2E2MU interventions within and between low risk, at risk, and high risk for suicide populations and the requisite expertise with these interventions, STRENGTHEN encourages proposals from multi-disciplinary mental health research teams and institutions that routinely conduct impactful and cost-effective neuroscience and clinical trials in populations that are low risk, at risk, or high risk for suicide.

DARPA is committed to reproducibility of studies and methods developed under its programs. In support of this ideal, performers will be required to pre-register their studies, methods, and hypotheses<sup>15</sup> and should clearly delineate within the proposal which proposed studies and methods will be exploratory and which will be confirmatory.

**Government Independent Verification and Validation (IV&V) (not being solicited under this BAA):** In addition to the TAs, STRENGTHEN will include a Government IV&V effort that will provide an assessment of the mechanistic models and neuroplastic interventions developed under TA1 and TA2, as well as offering insights into areas of particular interest to the Department of Defense regarding behavioral health and suicide.

## E. Technical Area Descriptions

The STRENGTHEN program comprises two TAs:

#### **TA1: Neuro-Mechanistic Models**

Neuroimaging approaches have enabled increasingly detailed models of dynamic brain networks, including networks related to CF and ER. However, numerous challenges remain. The brain regions responsible for CF and ER are widespread and implicated in numerous interrelated executive control and emotion processes. It is difficult to isolate and measure the neural mechanisms of CF and ER with ecological and construct validity. In addition, research indicates a high degree of individual variability of neurobehavioral network activation patterns, which means population-based studies are inadequate for individualized treatments. Furthermore, it remains unknown how changes in specific neural mechanisms of CF and ER within an individual lead to improved mental health outcomes. CF and ER are complicated, dynamic functions, which presents challenges both for their measurement, as well as for identifying the constituents of CF and ER that are most likely to lead to improved mental health outcomes.

TA1 will focus on the specification and measurement of individualized neurobiological markers of CF and ER that can be targeted by TA2 interventions. The result will establish the empirical relationship between CF and ER brain networks and mental health, thereby specifying biomechanistic protective factors for suicide and transdiagnostic behavioral health prevention at the level of the individual. Although previous work has demonstrated that CF and ER networks can be imaged, there is to date no definitive measure of the neurobiological protective mechanisms for either. Converging evidence indicates CF and ER rely on dynamic interactions

<sup>&</sup>lt;sup>15</sup> See pre-registration sites for instructions on how to pre-register a study. For example: <u>https://help.osf.io/hc/en-us/articles/360019738834-Create-a-Preregistration</u>. For more information about the purpose of pre-registration see <u>https://www.sciencemag.org/news/2018/09/more-and-more-scientists-are-preregistering-their-studies-should-you</u>

between multiple large-scale brain networks,<sup>16</sup> with the Salience Network (SN), Central Executive Network (CEN), and Default Mode Network (DMN) of Menon's Triple Network Model of Psychopathology (Triple Network Model) playing important roles.<sup>17,18,19</sup> Therefore, to identify an individual's neurobiological protective mechanisms of CF and ER, performers will need to develop and validate novel multi-dimensional models of CF and ER in longitudinal studies to assess the relationship between these models and behavioral outcomes. Data collection for longitudinal studies should, at a minimum, be throughout each phase.

Proposals must describe a detailed approach to develop and validate the brain network models for CF and ER for TA1, including:

- An approach to assessing the neurobiological protective mechanisms of CF and ER. Individualized brain networks should be activated and imaged to capture individual brain network activation patterns (see key processes, section I.C). Proposals are encouraged, but not limited, to include strategies to assess CF and ER as a function of the Triple Network Model.
- Brain imaging methodology and technology, including equipment and scan time.
- Decoding and analytic methodology to model brain networks and measure neuroprotective mechanisms of CF and ER.
- Validation methodology, including the cognitive-behavioral tasks that will be employed for behavioral validation and a methodology for separately developing (e.g., calibration) and validating (e.g., validation sample) the models. In addition, proposers are encouraged to further establish construct validity through additional analyses, which may include but is not limited to assessment of convergent validity, discriminant validity, reliability, and sensitivity to change.
- Iteratively refining their model to achieve greater predictive precision across the phases.
- Ensuring and/or assessing generalizability of developed brain network models relative to human diversity (e.g., race, ethnicity, age, gender, disability, language).

Proposers might consider the following fundamental questions related to individualized neurobehavioral models (we provide CF examples for convenience but proposers might ask parallel questions for ER):

<sup>18</sup> Xiao M, Chen X, Yi H, Luo Y, Yan Q, Feng T, He Q, Lei X, Qiu J, Chen H. Stronger functional network connectivity and social support buffer against negative affect during the COVID-19 outbreak and after the pandemic peak. Neurobiology of stress. 2021;15:100418. <u>https://doi.org/10.1016/j.ynstr.2021.100418</u>

<sup>&</sup>lt;sup>16</sup> Morawetz C, Riedel MC, Salo T, Berboth S, Eickhoff SB, Laird AR, Kohn N. Multiple large-scale neural networks underlying emotion regulation. Neuroscience & Biobehavioral Reviews. 2020;116:382-95. https://doi.org/10.1016/j.neubiorev.2020.07.001

<sup>&</sup>lt;sup>17</sup> Uddin LQ. Brain mechanisms supporting flexible cognition and behavior in adolescents with autism spectrum disorder. Biological psychiatry. 2021;89(2):172-83. <u>https://doi.org/10.1016/j.biopsych.2020.05.010</u>

<sup>&</sup>lt;sup>19</sup> Seeley, W. W. (2019). Seeley WW. The salience network: a neural system for perceiving and responding to homeostatic demands. Journal of Neuroscience. 2019;39(50):9878-82. <u>https://doi.org/10.1523/JNEUROSCI.1138-17.2019</u>

- What neurocognitive tests (1) are most strongly associated with trauma-related symptoms and/or wellbeing, (2) activate the targeted networks during imaging, and (3) have greatest potential for transition to clinical use?
- What aspects of CF (salience detection and attention, working memory, inhibition, task switching) would have the greatest protective, transdiagnostic, and well-being impact?
- Optimization of which networks of CF (shifting, updating, inhibition) would have the greatest protective impacts on wellbeing across behavioral health disorders?
- What set of C2E2MU intervention techniques will target specific interrelated networks associated with cognitive rigidity and/or repetitive negative thinking (mid-cinguloinsular, medial, and lateral frontoparietal)?
- What combination of spatial temporal neuroimaging techniques best balances targeting and scalability for low risk, at risk, high risk, of suicide populations?

These questions are provided solely to further contextualize TA1; proposals need not address them explicitly.

## **TA1 Objectives by Phase**

- Phase 1 (Base)- Develop approach to modeling CF and ER brain networks.
  - Use previously collected data to provide initial proof of concept validation and method refinement. Example sources of previously collected data include, but are not limited, to the National Institute of Health (NIH) Human Connectome Project, NIH Adolescent Brain Cognitive Development Study, and the UK Biobank, or performers' own prior research.
  - Develop individualized CF and ER brain network models employing validated neuroimaging paradigms. Phase 1 effort will focus on initial development and proof of concept, including correlation of individualized brain network models with CF and ER behavioral outcomes (e.g., error rates and response times).
  - Assess brain network models in at least one risk population (low risk, at risk, high risk).
- Phase 2 (Option) Refine the measurement model.
  - During Phase 2 performers will revise the brain network models of CF and ER and re-test predictive validity for greater precision. Proposers should include a description of their plan to assess and refine CF and ER brain network models for greater precision measurement of CF and ER behavioral responses.
  - Assess brain network models in at least two risk populations.
- Phase 3 (Notional) Establish ecological validity of the CF and ER brain network models.
  - During Phase 3 DARPA anticipates that performers will again revise the brain network models of CF and ER and re-test predictive validity, with the goal of optimizing the CF and ER brain network model's ability to predict CF and ER

behavioral response. Phase 3 objectives are provided for planning purposes only. Final Phase 3 objectives will be delineated in the proposal instructions issued near the end of Phase 2.

• Assess brain network models in all three risk populations.

#### **TA1 Impact Assessment**

- Proposals must include methodology for developing dose response curves as impact assessments. The dose response curve must quantify the relationship between CF and ER neurobehavioral models and the following three behavioral health outcome categories:
  - Psychological wellbeing (e.g., measures of mental resilience such as the emotional styles questionnaire [ESQ])
  - Suicide and self-injurious thoughts and behaviors (e.g., as captured by the self-injurious thoughts and behaviors interview [SITBI])
  - Mental health distress, symptoms, and/or diagnoses (e.g., measures of specific relevant diagnoses like the beck depression inventory [BDI] or validated, comprehensive assessment of behavioral health)
- Proposers should clearly identify measures for each category of behavioral health outcomes and provide justification for their choice of measures.

#### **TA2:** Neuroplastic Interventions

Combining complementary internal and/or external interventions to target individuals' CF and ER brain networks could create novel bioprotective factors to traumatic stress associated with mental illness and suicide. Emerging evidence demonstrates that single C2E2MU interventions induce neuroplastic changes in the brain while improving mental illness symptoms. However, combining these different interventions for synergistic impact on well-being and symptom reduction remains largely unexamined. To our knowledge, no attempts have been made to combine interventions to increase an individual's CF and ER as bioprotective factors against the impact of traumatic stress or as transdiagnostic approaches to repair network dysfunctions associated with traumatic stress and behavioral health challenges. STRENGTHEN seeks to develop hybrid interventions that can induce measurable, lasting changes in CF and ER brain networks.

In TA2 performers will leverage the complementary effects of different internal and external C2E2MU interventions into a hybrid intervention approach to optimize the neurobiological protective mechanisms of CF and ER.

Proposals must describe in detail their proposed clinical study design:

- Intervention design:
  - Description of each C2E2MU intervention that will be included through Phases 1 and 2, and are anticipated to continue in Phase 3, including a description of the specific brain network impacts targeted by each intervention.
  - o Description of the hybrid intervention approach that includes rationale for specific

intervention C2E2MU combinations, such as expected additive and/or synergistic effects on CF and ER brain circuits.

- Proposals are encouraged, but not limited, to interventions that target the Triple Network Model or similar multi-dimensional brain models.
- Research design:
  - Describe the clinical study design, including but not limited to assessment timing (baseline, post, follow up, etc.), number of arms, active controls, and subject assignment as applicable.
  - STRENGTHEN is intended to primarily test pre-post intervention response on CF and ER neural mechanisms as proof of concept and to establish the basis for future randomized controlled clinical trials. As such, large scale randomized controlled trials are not expected.
- Subject recruitment and retention:
  - Specify which populations (low risk, at risk, high risk) they will focus on in Phases 1 and 2, as well as subject recruitment and retention plans.
  - Describe subject recruitment plans and timelines for intervention testing in Phase 1 and 2 (e.g., projected recruitment by month).
  - Studies with military or veteran populations are encouraged but not required.
- Measures:
  - Describe target primary and secondary health outcomes, impact assessments, any additional proposed measures, and data collection plan.
  - Primary outcomes must include brain network changes, CF and ER behaviors, and CF and ER self-report scales.
  - Secondary outcomes must include health impacts, including but not limited to positive impacts on wellbeing, mental illness symptoms (e.g., depression, anxiety, PTSD symptoms), and suicide/self-injurious thoughts and behaviors.
  - The data collection plan should include, but is not limited to, imaging methods, scan time, behavioral measures, self-report measures, and data collection timelines.
- Analytic plan:
  - Proposals must include a power analysis including planned subject pool sizes and expected effect sizes to justify the soundness of the proposed research design.
  - Proposals must include a statistical analysis plan for assessing primary and secondary outcomes of hybrid interventions.

Based on the goals of TA2, proposals might consider the following fundamental questions related to individualized hybrid interventions:

• What current single C2E2MU intervention paradigms could serve as baselines of

comparison to evaluate hybrid effects (e.g., increasing intervals between need for IV ketamine doses for suicidal ideation or decreasing number of TMS treatments for depression)?

- What combinations of C2E2MU interventions would be most appropriate and scalable for increasing well-being in the low risk for suicide population?
- What combinations of C2E2MU interventions would be most appropriate for at risk and high risk for suicide populations?
- What technologies could be combined to target both cortical and limbic structures (e.g., transcranial direct current stimulation [tDCS] plus non-invasive vagus nerve stimulation [VNS] or TMS plus LFUS) for multi-dimensional interventions?
- What sequence of C2E2MU interventions could maximize synergistic effects (e.g., exercise prior to mindfulness meditation or mindfulness meditation prior to ECT)?

These questions are provided solely to further contextualize TA2; proposals need not address them explicitly.

## TA2 Objectives by Phase

- Phase 1 (Base) Designing a hybrid intervention
  - Design and test a hybrid intervention approach consisting of one internal and one external C2E2MU intervention.
  - The hybrid intervention can be the same across all risk populations or tailored to each population.
  - Test hybrid intervention in at least one risk population (low risk, at risk, high risk).
- Phase 2 (Option) Enhance the hybrid intervention
  - Evaluate ability to increase treatment response through adding an additional intervention to the hybrid intervention approach.
  - The additional intervention may be either an additional internal or an additional external intervention.
  - Proposers may propose to test only one additive intervention or to test different additions based on target population.
  - Test intervention in at least two risk populations.
- Phase 3 (Notional) Optimize hybrid intervention (Note Phase 3 objectives are provided for planning purposes only and will not be evaluated. Final Phase 3 objectives will be delineated in the proposal instructions issued near the end of Phase 2.)
  - Refine and tailor hybrid interventions to maximize synergistic and sustaining benefits for each target population (low risk, at risk, high risk).
  - Hybrid interventions can be the same across all populations, tailored to each study population, or based on a novel personalized medicine rubric that performers

develop leveraging CF and ER brain network assessments.

- Intensity, duration, number of interventions, and other variables identified by performers may be varied (e.g., increased or decreased) by population.
- Test in all three risk populations.

#### **TA2 Impact Assessment**

- Proposals must include methodology for developing time-to-onset and duration effect response curves as impact assessments. The time-to-onset curves quantify the time to change relationship following initiation of intervention, establishing the relationship treatment start and effect on behavioral health outcomes. Duration effect curves quantify the change over time following end of intervention, establishing the sustained treatment effects on behavioral health. Effect onset and duration effect curves must be developed for the following outcome categories:
  - Psychological wellbeing
  - Suicide and self-injurious thoughts and behaviors
  - o Mental health distress, symptoms, and/or diagnoses
- Proposers should clearly identify measures for each category of behavioral health outcomes and provide justification for their choice of measures.
- Proposer may choose to develop time-to-onset and duration-of-effect curves for each outcome within each population or based on matching of behavioral health outcomes to population (e.g., general mental distress in low risk, depression in at risk, suicidality in high risk populations; psychological wellbeing in all populations).

#### F. Schedule/Milestones

Performers' progress will be evaluated using the metrics and milestones enumerated below. Attainment of the milestones (indicated by month after award) and metrics for a given phase does not guarantee transition into the next phase of the program. Individual efforts will also be assessed on their expected ability to attain subsequent milestones and their expected ability to have a transformative impact on DoD and DARPA priorities.

#### **Technical and Management Milestones**

Significant program milestones geared to show progress are listed in Tables X and Y and should be integrated into proposed efforts. If these milestones are not applicable to a particular approach, appropriate alternative milestones at similar intervals must be proposed, and proposers should provide significant justification. In addition to the programmatic milestones, proposals should include additional quantifiable objectives and milestones, as appropriate, to reflect progress towards goals with at least 3 to 4-month intervals.

Additionally, STRENGTHEN will conduct regular Program/Peer Review meetings for Principal Investigators to share progress, results, best practices, and lessons learned with fellow performers, IV&V, and DARPA. Review meetings are anticipated to occur every 4-6 months and to be composed of a combination of virtual and in-person attendance. For budget planning purposes, proposers should assume one two-day review meetings per year with in-person attendance at locations split between the East and West Coasts of the United States. In person attendance should be limited to small core teams, including the Principal Investigator and key personnel. Virtual meetings may be held in place of in-person meetings depending on any travel restrictions that may exist during the program.

Notional Phase 3 milestones are included for planning purposes only. Final Phase 3 milestones will be delineated in the proposal instructions issued near the end of Phase 2.

	Month-after-	TA1 Milestone
	award	
	2	Collaborative program review of individualized modeling
		strategies; Preregistration of studies
	3	Submission of Independent Review Board (IRB)-approved
		protocol(s) for Human Subjects Research for secondary Human
Phase I		Research Protection Office (HRPO) review
(18 mo)	10	Preliminary validation of Phase 1 modeling strategy both at
		baseline and following interventions
	15	Phase 1 evaluation of program metrics
	18	Phase 1 summary report
	20	Revised modeling strategy with additive intervention
Phase 224Preliminary cross-validation of Phase 2 modeling		Preliminary cross-validation of Phase 2 modeling strategy
(12 mo)	<b>2 mo)</b> 28 Phase 2 evaluation of program metrics	
	30	Phase 2 summary report
Notional	32	Revised modeling strategy to optimize intervention impact
Phase 3	36	Preliminary cross-validation of Phase 3 modeling strategy
(12 mo)	42	Phase 3 summary report

**Table X - STRENGTHEN TA1 Milestones** 

#### Table Y - STRENGTHEN TA2 Milestones

	Month-after-	TA2 Milestone
	award	
	2	Collaborative program review of hybrid interventions and proposed
		CF and ER and health outcome targets; Preregistration of studies
	3	Submission of Independent Review Board (IRB)-approved
Dhaga 1		protocol(s) for Human Subjects Research for secondary Human
Phase I		Research Protection Office (HRPO) review
(18 mo)	10	Progress review of Phase 1 hybrid intervention trials, including
		review of preliminary data
	15	Phase 1 evaluation of program metrics and impact assessments
	18	Phase 1 summary report
Phase 2	20	Refined additive intervention and clinical assessment strategy;
(12 mo)		Updated regulatory submissions (as necessary)

	24 Progress review of Phase 2 hybrid intervention trials, inc review of preliminary data		
28 Phase 2 evaluation of program metrics and impacts as			
	30	Phase 2 summary report	
	32	Refined optimized intervention and clinical assessment strategy;	
Notional		Updated regulatory submissions (as necessary)	
Phase 3	36	Progress review of Phase 3 hybrid intervention trials, including	
(12 mo)		review of preliminary data	
	42	Phase 3 summary report	

The study preregistration referenced in Section I.D includes registration of all experimental and analysis plans (hypotheses, predicted outcomes and anticipated effect sizes, design, protocols, cross-validation strategy, analysis methods, etc.) for both modeling (TA1) and clinical (TA2) studies and for all populations proposed (low risk, at risk, high risk). Preregistered study plans will be will be shared with all performers. Preregistration does not preclude performers from integrating additional exploratory analytics into the research effort.

## **Program Metrics**

#### TA1

In order to meet the goals of STRENGTHEN, performers must develop brain network models for both CF and ER in TA1 that meet the following accuracy thresholds to demonstrate validity in predicting behavioral response. Notional Phase 3 metrics are included for planning purposes only. Final Phase 3 metrics will be delineated in the proposal instructions issued near the end of Phase 2.

TA1 Metric	Phase 1 (Base)	Phase 2 (Option)	Phase 3 (Notional)
Neurobiological prediction of CF behavioral response (e.g., ID/ED shift)	$R^2 = .60$	$R^2 = .70$	$R^2 = .85$
Neurobiological prediction of ER behavioral response (e.g., Emotional Stroop)	$R^2 = .60$	$R^2 = .70$	$R^2 = .85$

#### Table X: TA1 metrics by phase

Note that TA1 metrics for prediction of behavioral response require two conditions. First, proposals must address specific target neurobiological mechanisms of CF and ER and how network activity and/or connectivity will be measured within individuals. Second, the metric requires validated cognitive-behavioral response tasks, and proposals must describe the tasks to be employed to measure behavioral response. Proposals should present a clear and detailed description of how the neurobiological mechanisms being modeled are related to the specific behavioral tasks being employed. Performers are expected to meet metrics for both CF and ER.

Model validation assessments include (but are not restricted to) testing whether CF and ER can be assessed using brain network measurement parameters established prior to the collection and analysis of the cross-validation data. Model validation data should include data collected both before and following interventions and could correspond to data collected in different individuals or in the same individual but at different points in time.

## TA2

In order to meet the goals for the STRENGTHEN program, performers will demonstrate hybrid interventions to target (Phase 1), enhance (Phase 2), and notionally, optimize (Phase 3) the functioning of CF and ER brain networks in the greatest number of people. Performers will be required to meet metrics related to treatment response (% of participants demonstrating a clinically meaningful treatment response in both CF and ER following conclusion of the intervention protocol) and duration of treatment response (% of participants with sustained treatment response 1-month to 3-months post-treatment). Proposers must specify and justify what a clinically meaningful treatment response is for their proposed impact assessment(s). Notional Phase 3 metrics are included for planning purposes only. Final Phase 3 metrics will be delineated in the proposal instructions issued near the end of Phase 2.

TA2 Metric	Phase 1 (Base)	Phase 2 (Option)	Phase 3 (Notional)
CF and ER treatment	> 30%	> 45%	> 60%
response at 1 week			
Sustainment of	> 15% at 1 month	> 30% at 1 month	>45% at 3 months
treatment response			

Table Y: TA2 metrics by phase

To determine clinically meaningful treatment response, performers must develop dose response curves (as described for the TA1 Impact Assessment [see Section I.D]). Proposals must describe their approach to determining a clinically meaningful change in CF and ER based on the dose response curves and their proposed primary outcome metric for this determination. Clinically meaningful change in CF and ER should be based on how much change in CF and ER is necessary to produce meaningful improvement in psychological wellbeing, mental health distress/symptoms, and/or suicidality. Treatment response rates must be based on Intention to Treat (ITT) or modified ITT (mITT) analyses. If proposing mITT models, proposals must include description of and rationale for the proposed exclusions to an ITT model.

## **Other program Properties**

Both TA1 and TA2 must assume human subject testing will be considered Human Subjects Research (HSR) and plan for the Institutional Review Board (IRB) and secondary Human Research Protection Office (HRPO) reviews that are necessary for Government-sponsored HSR in the proposed cost and schedule. No HSR data collection can begin prior to HRPO approval. Performers can submit IRB approved protocols to HRPO for secondary review any time after contract award but will be required to submit them to HRPO for secondary review no later than 3 months after award (see Schedule/Milestones). To meet this deadline, proposers should submit protocols to their organization's IRB for initial approval with sufficient lead time for the necessary IRB approvals to be in place to support the HRPO submissions. Proposers are encouraged to include a draft IRB protocol for initial test investigations and/or a plan for submission to and review by an Institutional Review Board (IRB) with proposals as an appendix to Attachment D: PROPOSAL TEMPLATE VOLUME 1: TECHNICAL & MANAGEMENT to show feasibility of the regulatory approval timeline; this paperwork will not count against the page limit. Animal testing is out of scope as it will not be necessary to achieve STRENGTHEN's goals.

No efforts under either TA are anticipated to generate information subject to Controlled Unclassified Information (CUI) or Controlled Technical Information (CTI) controls, however proposer should refer to Section IV.B.4. for additional information if they are unsure whether their proposed effort may generate CUI or CTI. Note, efforts that produce Personal Identifiable Information (PII) in the course of working with human subjects will be expected to safeguard this data appropriately; DARPA will not be collecting any PII in the course of this program.

- Proposers should provide a technical and programmatic strategy that conforms to the entire program schedule and presents an aggressive plan to fully address all program goals, metrics, milestones, and deliverables.
- The task structure must be consistent across the proposed schedule, Statement of Work, and cost volume.
- A target start date of October 2023 may be assumed for planning purposes.
- Schedules will be synchronized across performers, as required, and monitored/revised as necessary throughout the program.
- All proposals must include the following meetings and travel in the proposed schedule and costs:
  - To continue integration and development between TAs, foster collaboration between teams and disseminate program developments, STRENGTHEN will conduct regular Program/Peer Review meetings, see Section F. Schedule/Milestones for notional meeting timing and strategy that can be used for budgeting purposes.
  - Regular teleconference meetings will be scheduled with the Government team for progress reporting as well as problem identification and mitigation. Proposers should anticipate at least one site visit per phase by the DARPA Program Manager during which they will have the opportunity to demonstrate progress towards agreed-upon milestones.

## G. Deliverables

Performers will be expected to provide at a minimum the following deliverables:

- Monthly progress reports, including both technical and financial.
- Comprehensive quarterly technical reports due within ten days of the end of the given quarter, describing progress made on the specific milestones as laid out in the SOW.
- A phase completion report submitted within 30 days of the end of each phase, summarizing the research done.
- Phase 1 and Phase 2 evaluation reports, including program metrics and impact assessments (see tables X and Y).
- Other negotiated deliverables specific to the objectives of the individual efforts. These may include registered reports; experimental protocols; human subjects research

regulatory submissions; publications; data management plan; intermediate and final versions of software libraries, code, and APIs, including documentation and user manuals; and/or a comprehensive assemblage of design documents, models, modeling data and results, and model validation data.

• Reporting as outlined in Section VI.C.

## H. Other Program Objectives and Considerations

#### 1. Collaboration

Throughout the course of the program, it is likely to be necessary for all performers—regardless of category (academic, industry, and government)—to share relevant information regarding their research and development to support the larger program goals. DARPA expects all program performers to work collaboratively with one another to realize the program objectives outlined herein. All proposals should describe plans for ensuring transparency of their processes to enable interactions and sharing of procedures and findings with other program performers and government transition partners. Proposals that fail to include these plans may be deemed non-conforming and removed from consideration.

#### 2. Intellectual Property

As discussed above, there is an emphasis on creating and using open source technologies, measurements, and interventional approaches. Data sharing and collaboration are key aspects of this program. Therefore, DARPA requires Government Purpose Rights at a minimum for all deliverables, but strongly prefers teams make no intellectual property claims so program products are aligned with open source regimes. See Section VI.B.4 for more information related to intellectual property.

#### **II. Award Information**

## A. General Award Information

#### DARPA anticipates multiple awards.

The level of funding for individual awards made under this BAA will depend on the quality of the proposals received and the availability of funds. Awards will be made to proposers<sup>20</sup> whose proposals are determined to be the most advantageous to the Government, all evaluation factors considered. See Section V for further information.

The Government reserves the right to:

• select for negotiation all, some, one, or none of the proposals received in response to this solicitation;

<sup>&</sup>lt;sup>20</sup> As used throughout this BAA, "proposer" refers to the lead organization on a submission to this BAA. The proposer is responsible for ensuring that all information required by a BAA--from all team members--is submitted in accordance with the BAA. "Awardee" refers to anyone who might receive a prime award from the Government, including recipients of procurement contracts, cooperative agreements, or Other Transactions. "Subawardee" refers to anyone who might receive a subaward from a prime awarde (e.g., subawardee, consultant, etc.).

- make awards without discussions with proposers;
- conduct discussions with proposers if it is later determined to be necessary;
- segregate portions of resulting awards into pre-priced options;
- accept proposals in their entirety or select only portions of proposals for award;
- fund awards in increments with options for continued work at the end of one or more phases;
- request additional documentation once the award instrument has been determined (e.g., representations and certifications); and
- remove proposers from award consideration should the parties fail to reach agreement on award terms within a reasonable time or the proposer fails to provide requested additional information in a timely manner.

Proposals identified for negotiation may result in a procurement contract, cooperative agreement, or Other Transaction (OT), depending upon the nature of the work proposed, the required degree of interaction between parties, and other factors.

Proposers looking for innovative, commercial-like contractual arrangements are encouraged to consider requesting Other Transactions. To understand the flexibility and options associated with Other Transactions, consult <u>http://www.darpa.mil/work-with-us/contract-management#OtherTransactions</u>.

In accordance with 10 U.S.C. § 4022(f), the Government may award a follow-on production contract or Other Transaction (OT) for any OT awarded under this solicitation if: (1) that participant in the OT, or a recognized successor in interest to the OT, successfully completed the entire prototype project provided for in the OT, as modified; and (2) the OT provides for the award of a follow-on production contract or OT to the participant, or a recognized successor in interest to the OT.

In all cases, the Government contracting officer shall have sole discretion to select award instrument type, regardless of instrument type proposed, and to negotiate all instrument terms and conditions with selectees. DARPA will apply publication or other restrictions, as necessary, if it determines that the research resulting from the proposed effort will present a high likelihood of disclosing performance characteristics of military systems or manufacturing technologies that are unique and critical to defense. Any award resulting from such a determination will include a requirement for DARPA permission before publishing any information or results on the program. For more information on publication restrictions, see the section below on Fundamental Research

#### **B.** Fundamental Research

It is DoD policy that the publication of products of fundamental research will remain unrestricted to the maximum extent possible. National Security Decision Directive (NSDD) 189 defines fundamental research as follows:

'Fundamental research' means basic and applied research in science and engineering, the results of which ordinarily are published and shared broadly within the scientific

community, as distinguished from proprietary research and from industrial development, design, production, and product utilization, the results of which ordinarily are restricted for proprietary or national security reasons.

As of the date of publication of this solicitation, the Government expects that program goals as described herein may be met by proposed efforts for fundamental research and non-fundamental research. Some proposed research may present a high likelihood of disclosing performance characteristics of military systems or manufacturing technologies that are unique and critical to defense. Based on the anticipated type of proposer (e.g., university or industry) and the nature of the solicited work, the Government expects that some awards will include restrictions on the resultant research that will require the awardee to seek DARPA permission before publishing any information or results relative to the program.

University or non-profit research institution performance under this solicitation may include effort categorized as fundamental research. In addition to Government support for free and open scientific exchanges and dissemination of research results in a broad and unrestricted manner, the academic or non-profit research performer or recipient, regardless of tier, acknowledges that such research may have implications that are important to U.S. national interests and must be protected against foreign influence and exploitation. As such, the academic or non-profit research performer or recipient agrees to comply with the following requirements:

- (a) The University or non-profit research institution performer or recipient must establish and maintain an internal process or procedure to address foreign talent programs, conflicts of commitment, conflicts of interest, and research integrity. The academic or non-profit research performer or recipient must also utilize due diligence to identify Foreign Components or participation by Senior/Key Personnel in Foreign Government Talent Recruitment Programs and agree to share such information with the Government upon request.
  - i. The above described information will be provided to the Government as part of the proposal response to the solicitation and will be reviewed and assessed prior to award. Generally, this information will be included in the Research and Related Senior/Key Personnel Profile (Expanded) form (SF-424) required as part the proposer's submission through Grants.gov.
    - 1. Instructions regarding how to fill out the SF-424 and its biographical sketch can be found through Grants.gov.
  - ii. In accordance with USD(R&E) direction to mitigate undue foreign influence in DoD-funded science and technology, DARPA will assess all Senior/Key Personnel proposed to support DARPA grants and cooperative agreements for potential undue foreign influence risk factors relating to professional and financial activities. This will be done by evaluating information provided via the SF-424, and any accompanying or referenced documents, in order to identify and assess any associations or affiliations the Senior/Key Personnel may have with foreign strategic competitors or countries that have a history of intellectual property theft, research misconduct, or history of targeting U.S. technology for unauthorized transfer. DARPA's evaluation takes into consideration the entirety of the Senior/Key Personnel's SF-424, current and pending support, and biographical

sketch, placing the most weight on the Senior/Key Person's professional and financial activities over the last 4 years. The majority of foreign entities lists used to make these determinations are publicly available. The DARPA Countering Foreign Influence Program (CFIP) "Senior/Key Personnel Foreign Influence Risk Rubric" details the various risk ratings and factors. The rubric can be seen at the following link:

https://www.darpa.mil/attachments/092021DARPACFIPRubric.pdf

- iii. Examples of lists that DARPA leverages to assess potential undue foreign influence factors include, but are not limited to:
  - Executive Order 13959 "Addressing the Threat From Securities Investments That Finance Communist Chinese Military Companies": <u>https://www.govinfo.gov/content/pkg/FR-2020-11-17/pdf/2020-25459.pdf</u>
  - 2. The U.S. Department of Education's College Foreign Gift and Contract Report: <u>College Foreign Gift Reporting (ed.gov)</u>
  - 3. The U.S. Department of Commerce, Bureau of Industry and Security, List of Parties of Concern: <u>https://www.bis.doc.gov/index.php/policy-guidance/lists-of-parties-of-concern</u>
  - 4. Georgetown University's Center for Security and Emerging Technology (CSET) Chinese Talent Program Tracker: https://chinatalenttracker.cset.tech
  - 5. Director of National Intelligence (DNI) "World Wide Threat Assessment of the US Intelligence Community": <u>2021 Annual Threat Assessment of</u> <u>the U.S. Intelligence Community (dni.gov)</u>
  - 6. Various Defense Counterintelligence and Security Agency (DCSA) products regarding targeting of US technologies, adversary targeting of academia, and the exploitation of academic experts: <u>https://www.dcsa.mil/</u>
  - (b) DARPA's analysis and assessment of affiliations and associations of Senior/Key Personnel is compliant with Title VI of the Civil Rights Act of 1964. Information regarding race, color, or national origin is not collected and does not have bearing in DARPA's assessment.
  - (c) University or non-profit research institutions with proposals selected for negotiation that have been assessed as having high or very high undue foreign influence risk, will be given an opportunity during the negotiation process to mitigate the risk. DARPA reserves the right to request any follow-up information needed to assess risk or mitigation strategies.
- i. Upon conclusion of the negotiations, if DARPA determines, despite any proposed mitigation terms (e.g. mitigation plan, alternative research personnel), the participation of any Senior/Key Research Personnel still represents high risk to the program, or proposed mitigation affects the Government's confidence in proposer's capability to successfully complete the research (e.g., less qualified Senior/Key Research Personnel) the Government may determine not to award the proposed effort. Any decision not to award will be predicated upon reasonable

disclosure of the pertinent facts and reasonable discussion of any possible alternatives while balancing program award timeline requirements.

- (d) Failure of the academic or non-profit research performer or recipient to reasonably exercise due diligence to discover or ensure that neither it nor any of its Senior/Key Research Personnel involved in the subject award are participating in a Foreign Government Talent Program or have a Foreign Component with an a strategic competitor or country with a history of targeting U.S. technology for unauthorized transfer may result in the Government exercising remedies in accordance with federal law and regulation.
  - i. If, at any time, during performance of this research award, the academic or nonprofit research performer or recipient should learn that it, its Senior/Key Research Personnel, or applicable team members or subtier performers on this award are or are believed to be participants in a Foreign Government Talent Program or have Foreign Components with a strategic competitor or country with a history of targeting U.S. technology for unauthorized transfer , the performer or recipient will notify the Government Contracting Officer or Agreements Officer within 5 business days.
    - 1. This disclosure must include specific information as to the personnel involved and the nature of the situation and relationship. The Government will have 30 business days to review this information and conduct any necessary fact-finding or discussion with the performer or recipient.
    - 2. The Government's timely determination and response to this disclosure may range anywhere from acceptance, to mitigation, to termination of this award at the Government's discretion.
    - 3. If the University receives no response from the Government to its disclosure within 30 business days, it may presume that the Government has determined the disclosure does not represent a threat.
  - ii. The performer or recipient must flow down this provision to any subtier contracts or agreements involving direct participation in the performance of the research.

#### (e) Definitions

- i. Senior/Key Research Personnel
  - This definition would include the Principal Investigator or Program/Project Director and other individuals who contribute to the scientific development or execution of a project in a substantive, measurable way, whether or not they receive salaries or compensation under the award. These include individuals whose absence from the project would be expected to impact the approved scope of the project.
  - 2. Most often, these individuals will have a doctorate or other professional degrees, although other individuals may be included within this definition on occasion.
- ii. Foreign Associations/Affiliations

- 1. Association is defined as collaboration, coordination or interrelation, professionally or personally, with a foreign government-connected entity where no direct monetary or non-monetary reward is involved.
- 2. Affiliation is defined as collaboration, coordination, or interrelation, professionally or personally, with a foreign government-connected entity where direct monetary or non-monetary reward is involved.
- iii. Foreign Government Talent Recruitment Programs
  - 1. In general, these programs will include any foreign-state-sponsored attempt to acquire U.S. scientific-funded research or technology through foreign government-run or funded recruitment programs that target scientists, engineers, academics, researchers, and entrepreneurs of all nationalities working and educated in the U.S.
  - 2. Distinguishing features of a Foreign Government Talent Recruitment Program may include:
    - a. Compensation, either monetary or in-kind, provided by the foreign state to the targeted individual in exchange for the individual transferring their knowledge and expertise to the foreign country.
    - b. In-kind compensation may include honorific titles, career advancement opportunities, promised future compensation or other types of remuneration or compensation.
    - c. Recruitment, in this context, refers to the foreign-state-sponsor's active engagement in attracting the targeted individual to join the foreign-sponsored program and transfer their knowledge and expertise to the foreign state. The targeted individual may be employed and located in the U.S. or in the foreign state.
    - d. Contracts for participation in some programs that create conflicts of commitment and/or conflicts of interest for researchers. These contracts include, but are not limited to, requirements to attribute awards, patents, and projects to the foreign institution, even if conducted under U.S. funding, to recruit or train other talent recruitment plan members, circumventing merit-based processes, and to replicate or transfer U.S.-funded work in another country.
    - e. Many, but not all, of these programs aim to incentivize the targeted individual to physically relocate to the foreign state. Of particular concern are those programs that allow for continued employment at U.S. research facilities or receipt of U.S. Government research funding while concurrently receiving compensation from the foreign state.
  - 3. Foreign Government Talent Recruitment Programs DO NOT include:
    - a. Research agreements between the University and a foreign entity, unless that agreement includes provisions that create situations of concern addressed elsewhere in this section,

- b. Agreements for the provision of goods or services by commercial vendors, or
- c. Invitations to attend or present at conferences.
- iv. Conflict of Interest
  - 1. A situation in which an individual, or the individual's spouse or dependent children, has a financial interest or financial relationship that could directly and significantly affect the design, conduct, reporting, or funding of research.
- v. Conflict of Commitment
  - 1. A situation in which an individual accepts or incurs conflicting obligations between or among multiple employers or other entities.
  - 2. Common conflicts of commitment involve conflicting commitments of time and effort, including obligations to dedicate time in excess of institutional or funding agency policies or commitments. Other types of conflicting obligations, including obligations to improperly share information with, or withhold information from, an employer or funding agency, can also threaten research security and integrity and are an element of a broader concept of conflicts of commitment.
- vi. Foreign Component
  - 1. Performance of any significant scientific element or segment of a program or project outside of the U.S., either by the University or by a researcher employed by a foreign organization, whether or not U.S. government funds are expended.
  - 2. Activities that would meet this definition include, but are not limited to:
    - a. Involvement of human subjects or animals;
    - b. Extensive foreign travel by University research program or project staff for the purpose of data collection, surveying, sampling, and similar activities;
    - c. Collaborations with investigators at a foreign site anticipated to result in co-authorship;
    - d. Use of facilities or instrumentation at a foreign site;
    - e. Receipt of financial support or resources from a foreign entity; or
    - f. Any activity of the University that may have an impact on U.S. foreign policy through involvement in the affairs or environment of a foreign country.
  - 3. Foreign travel is not considered a Foreign Component.
- vii. Strategic Competitor

1. A nation, or nation-state, that engages in diplomatic, economic or technological rivalry with the United States where the fundamental strategic interests of the U.S are under threat.

Proposers should indicate in their proposal whether they believe the scope of the research included in their proposal is fundamental or not. While proposers should clearly explain the intended results of their research, the Government shall have sole discretion to determine whether the proposed research shall be considered fundamental and to select the award instrument type. Appropriate language will be included in resultant awards for non-fundamental research to prescribe publication requirements and other restrictions, as appropriate. This language can be found at <a href="http://www.darpa.mil/work-with-us/additional-baa">http://www.darpa.mil/work-with-us/additional-baa</a>.

For certain research projects, it may be possible that although the research to be performed by a potential awardee is non-fundamental research, its proposed subawardee's effort may be fundamental research. It is also possible that the research performed by a potential awardee is fundamental research while its proposed subawardee's effort may be non-fundamental research. In all cases, it is the potential awardee's responsibility to explain in its proposal which proposed efforts are fundamental research and why the proposed efforts should be considered fundamental research.

## **III. Eligibility Information**

## A. Eligible Applicants

All responsible sources capable of satisfying the Government's needs may submit a proposal that shall be considered by DARPA. Historically Black Colleges and Universities, Small Businesses, Small Disadvantaged Businesses and Minority Institutions are encouraged to submit proposals and join others in submitting proposals; however, no portion of this announcement will be set aside for these organizations' participation due to the impracticality of reserving discrete or severable areas of this research for exclusive competition among these entities.

# 1. Federally Funded Research and Development Centers (FFRDCs) and Government Entities

## 1. FFRDCs

FFRDCs are subject to applicable direct competition limitations and cannot propose to this solicitation in any capacity unless they meet the following conditions: (1) FFRDCs must clearly demonstrate, with specific details, that the proposed work, expertise, and facilities are not otherwise available from the private sector, and (2) FFRDCs must provide a letter, on official letterhead from their sponsoring organization, that (a) cites the specific authority establishing their eligibility to propose to Government solicitations and compete with industry, and (b) certifies the FFRDC's compliance with the associated FFRDC sponsor agreement's terms and conditions. These conditions are a requirement for FFRDCs proposing to be awardees or subawardees. FFRDC proposals that do not include these elements may be deemed non-conforming and removed from consideration.

## 2. Government Entities

Government Entities (e.g., Government/National laboratories, military educational institutions, etc.) are subject to applicable direct competition limitations. Government Entities must clearly demonstrate that the work is not otherwise available from the private sector and provide written documentation citing the specific statutory authority and contractual authority, if relevant, establishing their ability to propose to Government solicitations and compete with industry. This information is required for Government Entities proposing to be awardees or subawardees.

## 2. Authority and Eligibility

At the present time, DARPA does not consider 15 U.S.C. § 3710a to be sufficient legal authority to show eligibility. While 10 U.S.C.§ 4892 may be the appropriate statutory starting point for some entities, specific supporting regulatory guidance, together with evidence of agency approval, will still be required to fully establish eligibility. DARPA will consider FFRDC and Government Entity eligibility submissions on a case-by-case basis; however, the burden to prove eligibility for all team members rests solely with the proposer.

## 3. Other Applicants

Non-U.S. organizations and/or individuals may participate to the extent that such participants comply with any necessary nondisclosure agreements, security regulations, export control laws, and other governing statutes applicable under the circumstances.

## **B.** Organizational Conflicts of Interest

## FAR 9.5 Requirements

In accordance with FAR 9.5, proposers are required to identify and disclose all facts relevant to potential OCIs involving the proposer's organization and *any* proposed team member (subawardee, consultant). Under this Section, the proposer is responsible for providing this disclosure with each proposal submitted to the solicitation. The disclosure must include the proposer's, and as applicable, proposed team member's OCI mitigation plan. The OCI mitigation plan must include a description of the actions the proposer has taken, or intends to take, to prevent the existence of conflicting roles that might bias the proposer's judgment and to prevent the proposer from having unfair competitive advantage. The OCI mitigation plan will specifically discuss the disclosed OCI in the context of each of the OCI limitations outlined in FAR 9.505-1 through FAR 9.505-4.

## Agency Supplemental OCI Policy

In addition, DARPA has a supplemental OCI policy that prohibits contractors/performers from concurrently providing Scientific Engineering Technical Assistance (SETA), Advisory and Assistance Services (A&AS) or similar support services and being a technical performer. Therefore, as part of the FAR 9.5 disclosure requirement above, a proposer must affirm whether the proposer or *any* proposed team member (subawardee, consultant) is providing SETA, A&AS, or similar support to any DARPA office(s) under: (a) a current award or subaward; or (b) a past award or subaward that ended within one calendar year prior to the proposal's submission date.

If SETA, A&AS, or similar support is being or was provided to any DARPA office(s), the proposal must include:

- The name of the DARPA office receiving the support;
- The prime contract number;
- Identification of proposed team member (subawardee, consultant) providing the support; and
- An OCI mitigation plan in accordance with FAR 9.5.

#### Government Procedures

In accordance with FAR 9.503, 9.504 and 9.506, the Government will evaluate OCI mitigation plans to avoid, neutralize or mitigate potential OCI issues before award and to determine whether it is in the Government's interest to grant a waiver. The Government will only evaluate OCI mitigation plans for proposals that are determined selectable under the solicitation evaluation criteria and funding availability.

The Government may require proposers to provide additional information to assist the Government in evaluating the proposer's OCI mitigation plan.

If the Government determines that a proposer failed to fully disclose an OCI; or failed to provide the affirmation of DARPA support as described above; or failed to reasonably provide additional information requested by the Government to assist in evaluating the proposer's OCI mitigation plan, the Government may reject the proposal and withdraw it from consideration for award.

Include any OCIs affirmations and disclosures in Attachment G: VOLUME 3: ADMINISTRATIVE & NATIONAL POLICY REQUIREMENTS.

## C. Cost Sharing/Matching

Cost sharing is not required; however, it will be carefully considered where there is an applicable statutory condition relating to the selected funding instrument (e.g., OTs under the authority of 10 U.S.C. § 4022). Cost sharing is encouraged where there is a reasonable probability of a potential commercial application related to the proposed research and development effort.

For more information on potential cost sharing requirements for Other Transactions for Prototype, see <u>http://www.darpa.mil/work-with-us/contract-management#OtherTransactions</u>.

## **IV. Application and Submission Information**

Prior to submitting a full proposal, proposers are *strongly encouraged* to first submit an abstract as described below. This process allows a proposer to ascertain whether the proposed concept is (1) applicable to the STRENGTHEN BAA and (2) currently of interest. For the purposes of this BAA, applicability is defined as follows:

- The proposed concept is applicable to the technical areas described herein and includes effort towards both technical areas.
- The proposed work addresses all four of the key processes and is applicable to all three of the target populations described herein.
- The proposed concept is important to DSO's current investment portfolio.

- The proposed concept investigates an innovative approach that enables revolutionary advances, i.e., will not primarily result in evolutionary improvements to the existing state of practice.
- The proposed work has not already been completed (i.e., the research element is complete but manufacturing/fabrication funds are required).
- The proposer has not already received funding or a positive funding decision for the proposed concept (whether from DARPA or another Government agency).

Abstracts and full proposals that are not found to be applicable to the STRENGTHEN BAA as defined above may be deemed non-conforming<sup>21</sup> and removed from consideration. All abstracts and full proposals must provide sufficient information to assess the validity/feasibility of their claims as well as comply with the requirements outlined herein for submission formatting, content and transmission to DARPA. Abstracts and full proposals that fail to do so may be deemed non-conforming and removed from consideration. Proposers will be notified of non-conforming determinations via letter.

## A. Address to Request Application Package

This document contains all information required to submit a response to this solicitation. No additional forms, kits, or other materials are needed except as referenced herein. No request for proposal or additional solicitation regarding this opportunity will be issued, nor is additional information available except as provided at the SAM.gov website (<u>https://sam.gov/</u>), the Grants.gov website (<u>http://www.grants.gov/</u>), or referenced herein.

## B. Content and Form of Application Submission

## 1. Abstract Information and Formatting

As stated above, proposers are strongly encouraged to submit an abstract in advance of a full proposal to minimize effort and reduce the potential expense of preparing an out of scope proposal. All proposers are required to use Attachment A: ABSTRACT SUMMARY SLIDE TEMPLATE and Attachment B: ABSTRACT TEMPLATE provided with this solicitation on <a href="https://sam.gov/">https://sam.gov/</a> and <a href="https://sam.gov/">sam.gov/</a> and <a href="https://sam.gov/">sam.gov/</

The abstract provides a synopsis of the proposed project by including the following information:

- The proposed technical approach
- The technical rationale supporting the ability to achieve the metrics
- The technical and programmatic risks
- The makeup of the technical team (including the facilities and any proposed subcontractors)

<sup>&</sup>lt;sup>21</sup> "Conforming" is defined as having been submitted in accordance with the requirements outlined herein.

- High-level cost and schedule
- Availability of proposed staff

DARPA will respond to abstracts with a statement as to whether DARPA is interested in the idea. If DARPA does not recommend the proposer submit a full proposal, DARPA will provide feedback to the proposer regarding the rationale for this decision. Regardless of DARPA's response to an abstract, proposers may submit a full proposal. DARPA will review all conforming full proposals using the published evaluation criteria and without regard to any comments resulting from the review of an abstract.

Proposers should note that a favorable response to an abstract is not a guarantee that a proposal based on the abstract will ultimately be selected for award negotiation.

While it is DARPA policy to attempt to reply to abstracts within thirty calendar days, proposers to this solicitation may anticipate a response within approximately three weeks. These official notifications will be sent via email to the Technical POC and/or Administrative POC identified on the abstract coversheet.

## 2. Full Proposal Information and Formatting

#### a. Proposal Volumes

Full proposals must consist of all 3 volumes described below. To assist in proposal development, templates for these volumes are posted as attachments to this solicitation on <u>https://sam.gov/</u>. The templates are specific to each volume, as outlined below.

Full proposals requesting a procurement contract or Other Transaction (OT) must use the following attachments in each volume:

- Volume 1
  - Attachment C: PROPOSAL SUMMARY SLIDE TEMPLATE
  - Attachment D: PROPOSAL TEMPLATE VOLUME 1: TECHNICAL & MANAGEMENT
- Volume 2
  - Attachment E: PROPOSAL TEMPLATE VOLUME 2: COST
  - $\circ~$  Attachment F: MS Excel^{TM} DARPA COST PROPOSAL SPREADSHEET
- Volume 3
  - Attachment G: PROPOSAL TEMPLATE VOLUME 3: ADMINISTRATIVE & NATIONAL POLICY REQUIREMENTS

Full proposals requesting a cooperative agreement must use the following attachments in addition to the Grants.gov application package:

- Volume 1
  - Attachment C: PROPOSAL SUMMARY SLIDE TEMPLATE
  - Attachment D: PROPOSAL TEMPLATE VOLUME 1: TECHNICAL &

#### MANAGEMENT

- Volume 2\*
  - $\circ \quad \text{Attachment F: MS Excel^{\text{TM}} DARPA COST PROPOSAL SPREADSHEET}$
- Volume 3
  - Attachment G: PROPOSAL TEMPLATE VOLUME 3: ADMINISTRATIVE & NATIONAL POLICY REQUIREMENTS

\* Full proposals requesting a cooperative agreement do not need to include Attachment E. Instead, Budget Justification should be provided as Section L of the SF 424 Research & Related Budget form provided via <u>http://www.grants.gov</u> (see section IV.E.1.c for additional details). The Budget Justification should include the following information for the recipient and all subawardees:

- **Direct Labor (sections A and B)** Detail the total number of persons and their level of commitment for each position listed as well as which specific tasks (as described in the SOW) they will support.
- Equipment (section C) Provide an explanation for listed requested equipment exceeding \$5,000, properly justifying why it is required to meet the objectives of the program.
- **Travel (section D)** Provide the purpose of the trip, number of trips, number of days per trip, departure and arrival destinations, number of people, etc. (Note: The only travel included should be in direct support of the program. DARPA will not support generic conference travel [i.e., travel costs estimated for unidentified conferences]. DARPA will only consider travel costs for specified conferences, at which the traveller is presenting work generated by the STRENGTHEN program, and for which there is a direct benefit to the program's objectives.)
- Other Direct Costs (section F) Provide a justification for the items requested and an explanation of how the estimates were obtained.
- **Participant/Trainee Support Costs (section E)** Provide details on Tuition/ Fees/ Health Insurance, Stipends, Travel and Subsistence costs.

The Government requires that proposers\* use the provided MS Excel<sup>TM</sup> DARPA Standard Cost Proposal Spreadsheet in the development of their cost proposals. A customized cost proposal spreadsheet may be an attachment to this solicitation. If not, the spreadsheet can be found on the DARPA website at <u>http://www.darpa.mil/work-with-us/contract-management</u> (under "Resources" on the right-hand side of the webpage). All tabs and tables in the cost proposal spreadsheet should be developed in an editable format with calculation formulas intact to allow traceability of the cost proposal. This cost proposal spreadsheet should be used by the prime organization and all subcontractors. In addition to using the cost proposal spreadsheet, the cost proposal still must include all other items required in this announcement that are not covered by the editable spreadsheet. Subcontractor cost proposal spreadsheets may be submitted directly to the Government by the proposed subcontractor via e-mail to the address in Part I of this solicitation. **Using the provided cost proposal spreadsheet will assist the Government in a** 

## rapid analysis of your proposed costs and, if your proposal is selected for a potential award, speed up the negotiation and award execution process.

\*University proposers requesting a grant, cooperative agreement, or Other Transaction for Research do not need to use the MS Excel<sup>TM</sup> DARPA Standard Cost Proposal Spreadsheet. Instead, a proposed budget and justification may be provided using the SF-424 Research & Related Budget forms provided via <u>https://www.grants.gov</u>.

All proposers are required to use the appropriate templates based on the type of award requested. Templates are provided as attachments to this solicitation on <u>https://sam.gov/</u> and <u>http://www.grants.gov</u>. Full Proposals that do not include the appropriate attachments as detailed here may be deemed non-conforming and may not be evaluated.

## b. DARPA Embedded Entrepreneur Initiative (EEI)

Awardees pursuant to this solicitation may be eligible to participate in the DARPA Embedded Entrepreneurship Initiative (EEI) during the award's period of performance. EEI is a limited scope program offered by DARPA, at DARPA's discretion, to a small subset of awardees. The goal of DARPA's EEI is to increase the likelihood that DARPA-funded technologies take root in the U.S. and provide new capabilities for national defense. EEI supports DARPA's mission "to make pivotal investments in breakthrough technologies and capabilities for national security" by accelerating the transition of innovations out of the lab and into new capabilities for the Department of Defense (DoD). EEI investment supports development of a robust and deliberate Go-to-Market strategy for selling technology product to the government and commercial markets and positions DARPA awardees to attract U.S. investment. The following is for informational and planning purposes only and does not constitute solicitation of proposals to the EEI.

There are three elements to DARPA's EEI: (1) A Senior Commercialization Advisor (SCA) from DARPA who works with the Program Manager (PM) to examine the business case for the awardee's technology and uses commercial methodologies to identify steps toward achieving a successful transition of technology to the government and commercial markets; (2) Connections to potential industry and investor partners via EEI's Investor Working Groups; and (3) Additional funding on an awardee's contract for the awardee to hire an embedded entrepreneur to achieve specific milestones in a Go-to-Market strategy for transitioning the technology to products that serve both defense and commercial markets. This embedded entrepreneur's qualifications should include business experience within the target industries of interest, experience in commercializing early stage technology, and the ability to communicate and interact with technical and non-technical stakeholders. Funding for EEI is typically no more than \$250,000 per awardee over the duration of the award. An awardee may apportion EEI funding to hire more than one embedded entrepreneur, if achieving the milestones requires different expertise that can be obtained without exceeding the awardee's total EEI funding. The EEI effort is intended to be conducted concurrent with the research program without extending the period of performance.

## **EEI Application Process:**

After receiving an award under the solicitation, awardees interested in being considered for EEI should notify their DARPA Program Manager (PM) during the period of performance. Timing of

such notification should ideally allow sufficient time for DARPA and the awardee to review the awardee's initial transition plan, identify milestones to achieve under EEI, modify the award, and conduct the work required to achieve such milestones within the original award period of performance. These steps may take 18-24 months to complete, depending on the technology. If the DARPA PM determines that EEI could be of benefit to transition the technology to product(s) the Government needs, the PM will refer the performer to DARPA Commercial Strategy.

DARPA Commercial Strategy will then contact the performer, assess fitness for EEI, and in consultation with the DARPA technical office, determine whether to invite the performer to participate in the EEI. Factors that are considered in determining fitness for EEI include DoD/Government need for the technology; competitive approaches to enable a similar capability or product; risks and impact of the Government's being unable to access the technology from a sustainable source; Government and commercial markets for the technology; cost and affordability; manufacturability and scalability; supply chain requirements and barriers; regulatory requirements and timelines; Intellectual Property and Government Use Rights, and available funding.

Invitation to participate in EEI is at the sole discretion of DARPA and subject to program balance and the availability of funding. EEI participants' awards may be subsequently modified bilaterally to amend the Statement of Work to add negotiated EEI tasks, provide funding, and specify a milestone schedule which will include measurable steps necessary to build, refine, and execute a Go-to-Market strategy aimed at delivering new capabilities for national defense. Milestone examples are available at: <u>https://www.darpa.mil/work-with-us/contract-management</u>.

Awardees under this solicitation are eligible to be considered for participation in EEI, but selection for award under this solicitation does not imply or guarantee participation in EEI.

## 3. Proprietary Information

Proposers are responsible for clearly identifying proprietary information. Submissions containing proprietary information must have the cover page and each page containing such information clearly marked with a label such as "Proprietary" or "Company Proprietary." NOTE: "Confidential" is a classification marking used to control the dissemination of U.S. Government National Security Information as dictated in Executive Order 13526 and should not be used to identify proprietary business information.

**4.** Controlled Unclassified Information (CUI) and Controlled Technical Information (CTI) on Non-DoD Information Systems

Proposers and awardees are subject to the DoD requirements related to protection of CUI and CTI IAW Executive Order 13556, *Controlled Unclassified Information*, DFARS 252.204-7000, *Disclosure of Information*, DFARS 252.204-7012, *Safeguarding Covered Defense Information and Cyber Incident Reporting*, DoD Instruction 5200.48, Controlled Unclassified Information, DoD Instruction 8582.01, *Security of Non-DoD Information Systems Processing Unclassified Nonpublic DoD Information*. See <a href="http://www.darpa.mil/work-with-us/additional-baa">http://www.darpa.mil/work-with-us/additional-baa</a> for additional guidance on protecting CUI on Non-DoD Information Systems.

CUI is defined as unclassified information that requires safeguarding or dissemination controls,

pursuant to and consistent with applicable law, regulations, and Government-wide policies.

Controlled Technical Information (CTI) is defined as technical information with military or space application that is subject to controls on its access, use, reproduction, modification, performance, display, release, disclosure, or dissemination. The term CTI does not include information that is lawfully publicly available without restrictions.

DoD considers "technical information" to be technical data or computer software, as those terms are defined in Defense Federal Acquisition Regulation Supplement clause 252.227-7013, "Rights in Technical Data - Noncommercial Items" (48 CFR 252.227-7013). Examples of technical information include research and engineering data; engineering drawings and associated lists; specifications, standards, process sheets, manuals, technical reports, technical orders, catalogitem identifications, data sets, studies and analyses and related information; and computer software code. Note that such technical information may or may not be controlled (i.e., CTI), depending on whether it has military or space application.

Proposers should indicate in their proposal if their proposed solution includes CUI. All proposals indicating CUI requirements must include a draft CUI protection plan in Attachment G, PROPOSAL TEMPLATE VOLUME 3: ADMINISTRATIVE & NATIONAL POLICY REQUIREMENTS detailing how CUI will be protected at performance sites as well as sub-contractor locations. The draft CUI protection plan is not a source selection criterion, and there is no page limit. During selection and negotiation, DARPA will determine additional requirements and clarification required of the CUI protection plan. Potential award instruments for proposals containing CUI will be limited to contracts or Other Transactions.

As part of Attachment D: PROPOSAL TEMPLATE VOLUME 1: TECHNICAL & MANAGEMENT, the proposer should include a Statement of Work with a breakdown of all research tasks and subtasks and indicate the proposed classification for each. For all tasks and subtasks proposed to be unclassified, proposers should distinguish between work proposed to be Fundamental Research versus work proposed to be CUI. Proposers will provide a short explanation for why each subtask should be categorized as Fundamental Research or CUI.

If CUI tasks are proposed in the Statement of Work, proposers must provide a plan for protecting Controlled Unclassified Information as part of Attachment G: PROPOSAL TEMPLATE VOLUME 3: ADMINISTRATIVE & NATIONAL POLICY REQUIREMENTS, Section 8.

CTI is to be marked "DISTRIBUTION C. Distribution authorized to U.S. Government agencies and their contractors; Critical Technology; [current date]. Other requests for this document shall be referred to DARPA, DSO" in accordance with Department of Defense Instruction 5203.24, "Distribution of Statements on Technical Documents."

## 5. Security Information

DARPA anticipates that submissions received under this BAA will be unclassified. However, should a proposer wish to submit classified information, an *unclassified* email must be sent to the BAA mailbox requesting submission instructions from the DARPA/DSO Program Security Officer (PSO).

a. Program Security Information

## i. Program Security

Proposers should include with their proposal any proposed solution(s) to program security requirements unique to this program. Common program security requirements include but are not limited to: operational security (OPSEC) contracting/sub-contracting plans; foreign participation or materials utilization plans; program protection plans (which may entail the following) manufacturing and integration plans; range utilization and support plans (air, sea, land, space, and cyber); data dissemination plans; asset transportation plans; classified test activity plans; disaster recovery plans; classified material / asset disposition plans and public affairs / communications plans.

b. Controlled Unclassified Information (CUI)

For unclassified proposals containing controlled unclassified information (CUI), applicants will ensure personnel and information systems processing CUI security requirements are in place.

i. CUI Proposal Markings

If an unclassified submission contains CUI or the suspicion of such, as defined by Executive Order 13556 and 32 CFR Part 2002, the information must be appropriately and conspicuously marked CUI in accordance with DoDI 5200.48. Identification of what is CUI about this DARPA program may be provided at a later date via a CUI Guide.

ii. CUI Submission Requirements

Unclassified submissions containing CUI may be submitted via DARPA's BAA Website (<u>https://baa.darpa.mil</u>) in accordance with Part II Section VIII of this BAA.

iii. CUI Authorized Systems

Proposers submitting proposals involving the pursuit and protection of DARPA information designated as CUI must have, or be able to acquire prior to contract award, an information system authorized to process CUI information IAW NIST SP 800-171 and DoDI 8582.01.

The ability to perform classified work is not a requirement on this effort. However, it is possible that applications encountered during the execution of the contract may be classified. As such, may be useful for some performers to have access to classified information at up to the [INSERT LEVEL]. Therefore, if the proposer does have the ability to work at that level, the proposal should describe their organization's ability to perform classified work and their facilities' ability to receive and store classified materials as well as their ability and experience to perform work using classified information technology. This information should be included in Attachment G, PROPOSAL TEMPLATE VOLUME 3: ADMINISTRATIVE & NATIONAL POLICY REQUIREMENTS.

Security classification guidance and direction via a Security Classification Guide (SCG) and/or DD Form 254, "DoD Contract Security Classification Specification," will not be provided at this time, since DARPA is soliciting ideas only. If a determination is made that the award instrument may result in access to classified information, a SCG and/or DD Form 254 will be issued by DARPA and attached as part of the award.

## C. Submission Dates and Times

Proposers are warned that submission deadlines as outlined herein are in Eastern Time and will be strictly enforced. When planning a response to this solicitation, proposers should take into account that some parts of the submission process may take from one business day to one month to complete (e.g., registering for a SAM.gov Unique Entity Identifier (UEI) number or Taxpayer Identification Number (TIN)).

DARPA will acknowledge receipt of *complete* submissions via email and assign identifying numbers that should be used in all further correspondence regarding those submissions. If no confirmation is received within two business days, please contact the BAA Administrator at <u>STRENGTHEN@darpa.mil</u> to verify receipt.

## 1. Abstracts

Abstracts must be submitted per the instructions outlined herein *and received by DARPA* no later than the due date and time listed in Part One: Overview Information. Abstracts received after this time and date may not be reviewed.

## 2. Full Proposals

Full proposal packages as detailed in Section IV.B.2 above, and, as applicable, proprietary subawardee cost proposals and classified appendices to unclassified proposals, must be submitted per the instructions outlined herein *and received by DARPA* no later than the due date and time listed in Part One: Overview Information. Proposals received after this time and date may not be reviewed.

## **D.** Funding Restrictions

Not applicable.

## E. Other Submission Requirements

## 1. Unclassified Submission Instructions

Proposers must submit all parts of their submission package using the same method; submissions cannot be sent in part by one method and in part by another method nor should duplicate submissions be sent by multiple methods. Email submissions will not be accepted. Failure to comply with the submission procedures outlined herein may result in the submission being deemed non-conforming and withdrawn from consideration.

## a. Abstracts

DARPA/DSO will employ an electronic upload submission system (https://baa.darpa.mil/) for all UNCLASSIFIED abstracts sent in response to this solicitation. *Abstracts must not be submitted via Grants.gov or email.* Note: If an account has recently been created for the DARPA BAA Website, this account may be reused. Accounts are typically disabled and eventually deleted following 75-90 days of inactivity – if you are unsure when the account was last used, it is recommended that you create a new account. If no account currently exists for the DARPA BAA Website, visit the website to complete the two-step registration process. Submitters will need to

register for an Extranet account (by clicking "Create New Account" at the URL listed above) and wait for two separate e-mails containing a username and temporary password. After accessing the Extranet, submitters may then create an account for the DARPA BAA website (via the "Register your Organization" link along the left side of the homepage), view submission instructions, and upload/finalize the proposal. Note: Even if a submitter's organization has an existing registration, each user submitting a proposal must create their own Organization Registration.

All abstracts submitted electronically through DARPA's BAA Website must be uploaded as zip archives (i.e., files with a .zip or .zipx extension). The final zip archive should be no greater than 100 MB in size. Only one zip archive will be accepted per submission - subsequent uploads for the same submission will overwrite previous uploads, and submissions not uploaded as zip archives will be rejected by DARPA.

Proposers using the DARPA BAA Website may encounter heavy traffic on the submission deadline date; proposers should start this process as early as possible. Technical support for the DARPA BAA Submission website is available during regular business hours, Monday – Friday, 9:00 a.m. – 5:00 p.m. Requests for technical support must be emailed to <u>BAAT\_Support@darpa.mil</u> with a copy to <u>STRENGTHEN@darpa.mil</u>. Questions regarding submission contents, format, deadlines, etc. should be emailed to <u>STRENGTHEN@darpa.mil</u>. Questions/requests for support sent to any other email address may result in delayed/no response.

## b. Proposals Requesting a Procurement Contract or Other Transaction

Proposers requesting procurement contracts or Other Transactions may submit full proposals through ONE of the following methods: (1) electronic upload (DARPA-preferred); or (2) direct mail/hand-carry.

## i. Electronic Upload

DARPA/DSO encourages proposers to submit UNCLASSIFIED proposals via the DARPA BAA Submission website at <u>https://baa.darpa.mil</u>. Note: If an account has recently been created for the DARPA BAA Website, this account may be reused. Accounts are typically disabled and eventually deleted following 75-90 days of inactivity – if you are unsure when the account was last used, it is recommended that you create a new account. If no account currently exists for the DARPA BAA Website, visit the website to complete the two-step registration process. Submitters will need to register for an Extranet account (by clicking "Create New Account" at the URL listed above) and wait for two separate e-mails containing a username and temporary password. After accessing the Extranet, submitters may then create an account for the DARPA BAA website (via the "Register your Organization" link along the left side of the homepage), view submission instructions, and upload/finalize the proposal. Note: Even if a submitter's organization has an existing registration, each user submitting a proposal must create their own Organization Registration.

All unclassified proposals submitted electronically through DARPA's BAA Website must be uploaded as zip archives (i.e., files with a .zip or .zipx extension). The final zip archive should be no greater than 100 MB in size. Only one zip archive will be accepted per submission - subsequent uploads for the same submission will overwrite previous uploads, and submissions

not uploaded as zip archives will be rejected by DARPA.

Proposers using the DARPA BAA Website may encounter heavy traffic on the submission deadline date; proposers should start this process as early as possible. Technical support for the DARPA BAA Submission website is available during regular business hours, Monday – Friday, 9:00 a.m. – 5:00 p.m. Requests for technical support must be emailed to <u>BAAT\_Support@darpa.mil</u> with a copy to <u>STRENGTHEN@darpa.mil</u>. Questions regarding submission contents, format, deadlines, etc. should be emailed to <u>STRENGTHEN@darpa.mil</u>. Questions/requests for support sent to any other email address may result in delayed/no response.

## ii. Direct Mail/Hand-carry

Proposers electing to submit procurement contract or Other Transaction proposals via direct mail or hand-carried must provide one paper copy and one electronic copy on CD or DVD of the full proposal package. All parts of the proposal package must be mailed or hand-carried in a single delivery to the address noted in Section VII below.

## a. Proposals Requesting a Cooperative Agreement

Proposers requesting cooperative agreements must submit proposals through one of the following methods: (1) electronic upload per the instructions at <u>https://www.grants.gov/applicants/apply-for-grants.html</u> (DARPA-preferred); or (2) hard-copy mailed directly to DARPA. If proposers intend to use Grants.gov as their means of submission, then they must submit their entire proposal through Grants.gov; applications cannot be submitted in part to Grants.gov and in part as a hard-copy. Proposers using Grants.gov do not submit hard-copy proposals in addition to the Grants.gov electronic submission.

Submissions: In addition to the volumes and corresponding attachments requested elsewhere in this solicitation, proposers must also submit the three forms listed below.

Form 1: SF 424 Research and Related (R&R) Application for Federal Assistance, available on the Grants.gov website at <u>https://apply07.grants.gov/apply/forms/sample/RR\_SF424\_2\_0-V2.0.pdf</u>. *This form must be completed and submitted*.

To evaluate compliance with Title IX of the Education Amendments of 1972 (20 U.S.C. § 1681 et.seq.), the Department of Defense (DoD) is collecting certain demographic and career information to be able to assess the success rates of women who are proposed for key roles in applications in science, technology, engineering or mathematics disciplines. In addition, the National Defense Authorization Act (NDAA) for FY 2019, Section 1286, directs the Secretary of Defense to protect intellectual property, controlled information, key personnel, and information about critical technologies relevant to national security and limit undue influence, including foreign talent programs by countries that desire to exploit United States' technology within the DoD research, science and technology, and innovation enterprise. This requirement is necessary for all research and research-related educational activities. The DoD is using the two forms below to collect the necessary information to satisfy these requirements. Detailed instructions for each form are available on Grants.gov.

Form 2: The Research and Related Senior/Key Person Profile (Expanded) form, available on the Grants.gov website at

https://apply07.grants.gov/apply/forms/sample/RR\_KeyPersonExpanded\_3\_0-V3.0.pdf, will be

used to collect the following information for all senior/key personnel, including Project Director/Principal Investigator and Co-Project Director/Co-Principal Investigator, whether or not the individuals' efforts under the project are funded by the DoD. The form includes 3 parts: the main form administrative information, including the Project Role, Degree Type and Degree Year; the biographical sketch; and the current and pending support. The biographical sketch and current and pending support are to be provided as attachments:

- Biographical Sketch: Mandatory for Project Directors (PD) and Principal Investigators (PI), optional, but desired, for all other Senior/Key Personnel. The biographical sketch should include information pertaining to the researchers:
  - Education and Training.
  - Research and Professional Experience.
  - Collaborations and Affiliations (for conflict of interest).
  - o Publications and Synergistic Activities.
- Current and Pending Support: Mandatory for all Senior/Key Personnel including the PD/PI. This attachment should include the following information:
  - A list of all current projects the individual is working on, in addition to any future support the individual has applied to receive, regardless of the source.
  - Title and objectives of the other research projects.
  - The percentage per year to be devoted to the other projects.
  - The total amount of support the individual is receiving in connection to each of the other research projects or will receive if other proposals are awarded.
  - Name and address of the agencies and/or other parties supporting the other research projects
  - Period of performance for the other research projects.

Additional senior/key persons can be added by selecting the "Next Person" button at the bottom of the form. Note that, although applications without this information completed may pass Grants.gov edit checks, if DARPA receives an application without the required information, DARPA may determine that the application is incomplete and may cause your submission to be rejected and eliminated from further review and consideration under the solicitation. DARPA reserves the right to request further details from the applicant before making a final determination on funding the effort.

Form 3: <u>Research and Related Personal Data</u>, available on the Grants.gov website at <u>https://apply07.grants.gov/apply/forms/sample/RR\_PersonalData\_1\_2-V1.2.pdf</u>. Each applicant must complete the name field of this form, however, provision of the demographic information is voluntary. Regardless of whether the demographic fields are completed or not, this form must be submitted with at least the applicant's name completed.

## i. Electronic Upload

DARPA encourages cooperative agreement proposers to submit their proposals via electronic

upload at <u>http://www.grants.gov/web/grants/applicants/apply-for-grants.html</u>. Proposers electing to use this method must complete a one-time registration process on Grants.gov before a proposal can be electronically submitted. *If proposers have not previously registered, this process can take up to four weeks* so registration should be done in sufficient time to ensure it does not impact a proposer's ability to meet required submission deadlines. Registration requirements and instructions are outlined at <u>http://www.grants.gov/web/grants/register.html</u>.

Carefully follow the DARPA submission instructions provided with the solicitation application package on Grants.gov. Only the required forms listed therein (e.g., SF-424 and Attachments form) should be included in the submission. *NOTE: Grants.gov does not accept zipped or encrypted proposals.* 

Once Grants.gov has received an uploaded proposal submission, Grants.gov will send two email messages to notify proposers that: (1) the proposal has been received by Grants.gov; and (2) the proposal has been either validated or rejected by the system. *It may take up to two business days to receive these emails*. If the proposal is validated, then the proposer has successfully submitted their proposal. If the proposal is rejected, the submission must be corrected, resubmitted and revalidated before DARPA can retrieve it. If the solicitation is no longer open, the rejected proposal cannot be resubmitted. Once the proposal is retrieved by DARPA, Grants.gov will send a third email to notify the proposer. DARPA will send a final confirmation email as described in Section IV.C.

To avoid missing deadlines, Grants.gov recommends that proposers submit their proposals to Grants.gov 24-48 hours in advance of the proposal due date to provide sufficient time to complete the registration and submission process, receive email notifications and correct errors, as applicable.

Technical support for Grants.gov submissions may be reached at 1-800-518-4726 or <u>support@grants.gov</u>.

## ii. Direct Mail/Hand-carry

Proposers electing to submit cooperative agreement proposals via direct mail or hand-carried must provide one paper copy and one electronic copy on CD or DVD of the full proposal package. Proposers must complete the SF 424 R&R form (Application for Federal Assistance, Research and Related) provided at Grants.gov as part of the opportunity application package for this BAA\_and include it in the proposal submission. All parts of the proposal package must be mailed or hand-carried to the address noted in Section VII below.

## V. Application Review Information

## A. Evaluation Criteria

Proposals will be evaluated using the following criteria listed in descending order of importance: Overall Scientific and Technical Merit; Potential Contribution and Relevance to the DARPA Mission; and Cost and Schedule Realism.

## • Overall Scientific and Technical Merit

The proposed technical approach is innovative, feasible, achievable, and complete. The proposed technical team has the expertise and experience to accomplish the proposed tasks. Task descriptions and associated technical elements provided are complete and in a logical sequence with all proposed deliverables clearly defined such that a final outcome that achieves the goal can be expected as a result of award. The proposal identifies major technical risks, and planned mitigation efforts are clearly defined and feasible. The proposed schedule aggressively pursues performance metrics in an efficient time frame that accurately accounts for the anticipated workload.

## • Potential Contribution and Relevance to the DARPA Mission

The potential contributions of the proposed effort bolster the national security technology base and support DARPA's mission to make pivotal early technology investments that create or prevent technological surprise. The proposed intellectual property restrictions (if any) will not significantly impact the Government's ability to transition the technology.

## • Cost and Schedule Realism

The proposed costs and schedule are realistic for the technical and management approach and accurately reflect the technical goals and objectives of the solicitation. All proposed labor, material, and travel costs are necessary to achieve the program metrics, consistent with the proposer's statement of work and reflect a sufficient understanding of the costs and level of effort needed to successfully accomplish the proposed technical approach. The costs for the prime proposer and proposed subawardees are substantiated by the details provided in the proposal (e.g., the type and number of labor hours proposed per task, the types and quantities of materials, equipment and fabrication costs, travel and any other applicable costs and the basis for the estimates). Please note that the Phase 3 ROM is for budgetary purposes only and will not be evaluated. The proposed schedule aggressively pursues performance metrics in an efficient time frame that accurately accounts for the anticipated workload. The proposed schedule identifies and mitigates any potential schedule risk.

## **B.** Review and Selection Process

DARPA will conduct a scientific/technical review of each conforming proposal. Conforming proposals comply with all requirements detailed in this solicitation; proposals that fail to do so may be deemed non-conforming and may be removed from consideration. Proposals will not be evaluated against each other since they are not submitted in accordance with a common work statement. DARPA's intent is to review proposals as soon as possible after they arrive; however, proposals may be reviewed periodically for administrative reasons.

The review process identifies proposals that meet the evaluation criteria described above and are, therefore, selectable for negotiation of awards by the Government. DARPA policy is to ensure impartial, equitable, comprehensive proposal evaluations and to select proposals that meet DARPA technical, policy, and programmatic goals. Proposals that are determined selectable will not necessarily receive awards (see Section II). Selections may be made at any time during the period of solicitation. For evaluation purposes, a proposal is defined to be the document and supporting materials as described in Section IV.

## 1. Handling of Source Selection Information

DARPA policy is to treat all submissions as source selection information (FAR 2.101 and 3.104), and to only disclose their contents to authorized personnel. Restrictive notices notwithstanding, submissions may be handled by support contractors for administrative purposes and/or to assist with technical evaluation. All DARPA support contractors performing this role are expressly prohibited from performing DARPA-sponsored technical research and are bound by appropriate nondisclosure agreements. Subject to the restrictions set forth in FAR 37.203(d), DARPA may also request input on technical aspects of the proposals from other non-Government consultants/experts who are strictly bound by the appropriate non-disclosure requirements.

Submissions will not be returned. The original of each submission received will be retained at DARPA and all other non-required copies destroyed. A certification of destruction may be requested via email to the BAA mailbox, provided the formal request is received within 5 days after being notified of submission status.

## C. Countering Foreign Influence Program (CFIP)

DARPA's CFIP is an adaptive risk management security program designed to help protect the critical technology and performer intellectual property associated with DARPA's research projects by identifying the possible vectors of undue foreign influence. The CFIP team will create risk assessments of all proposed Senior/Key Personnel selected for negotiation of a fundamental research grant or cooperative agreement award. The CFIP risk assessment process will be conducted separately from the DARPA scientific review process and adjudicated prior to final award.

## D. Federal Awardee Performance and Integrity Information (FAPIIS)

Following the review and selection process described above, but prior to making an award above the simplified acquisition threshold (FAR 2.101), DARPA is required<sup>22</sup> to review and consider any information available through the designated integrity and performance system (currently FAPIIS). Selectees have the opportunity to comment on any information about themselves entered in the database. DARPA will consider any comments and other information in FAPIIS or other systems prior to making an award.

## VI. Award Administration Information

## A. Selection Notices

After proposal evaluations are complete, proposers will be notified as to whether their proposal was selected for award negotiation as a result of the review process. Notification will be sent by email to the Technical and Administrative POCs identified on the proposal cover sheet. If a proposal has been selected for award negotiation, the Government will initiate those negotiations following the notification.

## **B.** Administrative and National Policy Requirements

## 1. Solicitation Provisions and Award Clauses, Terms and Conditions

<sup>&</sup>lt;sup>22</sup> Per 41 U.S.C. § 2313, as implemented by FAR 9.103 and 2 CFR § 200.205.

Solicitation provisions relevant to DARPA BAAs are listed on the Additional BAA Content page on DARPA's website at <u>www.darpa.mil/work-with-us/additional-baa</u>. This page also lists award clauses that, depending on their applicability, may be included in the terms and conditions of awards resultant from DARPA solicitations. This list is not exhaustive and the clauses, terms and conditions included in a resultant award will depend on the nature of the research effort, the specific award instrument, the type of awardee, and any applicable security or publication restrictions.

For terms and conditions specific to grants and/or cooperative agreements, see the DoD General Research Terms and Conditions (latest version) at <u>http://www.onr.navy.mil/Contracts-Grants/submit-proposal/grants-proposal/grants-terms-conditions</u> and the supplemental DARPA-specific terms and conditions at <u>http://www.darpa.mil/work-with-us/contract-management#GrantsCooperativeAgreements</u>.

The above information serves to put potential proposers and awardees on notice of proposal requirements and award terms and conditions to which they may have to adhere.

## 2. System for Award Management (SAM) and Universal Identifier Requirements

All proposers must be registered in SAM unless exempt per FAR 4.1102. FAR 52.204-7, "System for Award Management" and FAR 52.204-13, "System for Award Management Maintenance" are incorporated into this solicitation. See <u>http://www.darpa.mil/work-with-us/additional-baa</u> for further information.

International entities can register in SAM by following the instructions in this link: <u>https://www.fsd.gov/sys\_attachment.do?sys\_id=c08b64ab1b4434109ac5ddb6bc4bcbb8</u>.

NOTE: New registrations can take an average of 7-10 business days to process in SAM. SAM registration requires the following information:

- SAM Unique Entity Identifier (UEI)
- TIN
- Commercial and Government Entity (CAGE) Code. If a proposer does not already have a CAGE code, one will be assigned during SAM registration.
- Electronic Funds Transfer information (e.g., proposer's bank account number, routing number, and bank phone or fax number).

## 3. Representations and Certifications

In accordance with FAR 4.1102 and 4.1201, proposers requesting a procurement contract must complete electronic annual representations and certifications at <u>https://www.sam.gov/</u>.

In addition, all proposers are required to submit for all award instrument types supplementary DARPA-specific representations and certifications at the time of proposal submission. See <a href="http://www.darpa.mil/work-with-us/reps-certs">http://www.darpa.mil/work-with-us/reps-certs</a> for further information on required representation and certification depending on your requested award instrument.

A small business joint venture offeror must submit, with its offer, the representation required in paragraph (c) of FAR solicitation provision 52.212-3, Offeror Representations and

Certifications-Commercial Products and Commercial Services, and paragraph (c) of FAR solicitation provision 52.219-1, Small Business Program Representations, in accordance with 52.204-8(d) and 52.212-3(b) for the following categories: (A) Small business; (B) Service-disabled veteran-owned small business; (C) Women-owned small business (WOSB) under the WOSB Program; (D) Economically disadvantaged women-owned small business under the WOSB Program; or (E) Historically underutilized business zone small business.

## 4. Intellectual Property

Proposers should note that the Government does not own the intellectual property or technical data/computer software developed under Government contracts. The Government acquires the right to use the technical data/computer software. Regardless of the scope of the Government's rights, awardees may freely use their same data/software for their own commercial purposes (unless restricted by U.S. export control laws or security classification). Therefore, technical data and computer software developed under this solicitation will remain the property of the awardees, though DARPA will have, at a minimum, Government Purpose Rights (GPR) to technical data and computer software developed through DARPA sponsorship.

If proposers desire to use proprietary computer software or technical data or both as the basis of their proposed approach, in whole or in part, they should: (1) clearly identify such software/data and its proposed particular use(s); (2) explain how the Government will be able to reach its program goals (including transition) within the proprietary model offered; and (3) provide possible nonproprietary alternatives in any area that might present transition difficulties or increased risk or cost to the Government under the proposed proprietary solution. Proposers expecting to use, but not to deliver, commercial open source tools or other materials in implementing their approach may be required to indemnify the Government against legal liability arising from such use.

All references to "Unlimited Rights" or "Government Purpose Rights" are intended to refer to the definitions of those terms as set forth in the Defense Federal Acquisition Regulation Supplement (DFARS) 227.

## a. Intellectual Property Representations

All proposers must provide a good faith representation of either ownership or possession of appropriate licensing rights to all other intellectual property to be used for the proposed project. Proposers must provide a short summary for each item asserted with less than unlimited rights that describes the nature of the restriction and the intended use of the intellectual property in the conduct of the proposed research. See Attachment G: PROPOSAL TEMPLATE VOLUME 3: ADMINISTRATIVE & NATIONAL POLICY REQUIREMENTS, Section 4.

## b. Patents

All proposers must include documentation proving ownership or possession of appropriate licensing rights to all patented inventions to be used for the proposed project. If a patent application has been filed for an invention, but it includes proprietary information and is not publicly available, a proposer must provide documentation that includes: the patent number, inventor name(s), assignee names (if any), filing date, filing date of any related provisional application, and summary of the patent title, with either: (1) a representation of invention

ownership; or (2) proof of possession of appropriate licensing rights in the invention (i.e., an agreement from the owner of the patent granting license to the proposer).

## c. Procurement Contracts

## i. Noncommercial Items (Technical Data and Computer Software)

Proposers requesting a procurement contract must list all noncommercial technical data and computer software that it plans to generate, develop, and/or deliver, in which the Government will acquire less than unlimited rights and to assert specific restrictions on those deliverables. In the event a proposer does not submit the list, the Government will assume that it has unlimited rights to all noncommercial technical data and computer software generated, developed, and/or delivered, unless it is substantiated that development of the noncommercial technical data and computer software occurred with mixed funding. If mixed funding is anticipated in the development of noncommercial technical data and computer software generated, developed, and/or delivered, proposers should identify the data and software in question as subject to GPR. In accordance with DFARS 252.227-7013, "Rights in Technical Data - Noncommercial Items," and DFARS 252.227-7014, "Rights in Noncommercial Computer Software and Noncommercial Computer Software Documentation," the Government will automatically assume that any such GPR restriction is limited to a period of 5 years, at which time the Government will acquire unlimited rights unless the parties agree otherwise. The Government may use the list during the evaluation process to evaluate the impact of any identified restrictions and may request additional information from the proposer, as may be necessary, to evaluate the proposer's assertions. Failure to provide full information may result in a determination that the proposal is non-conforming. A template for complying with this request is provided in Attachment G: PROPOSAL TEMPLATE VOLUME 3: ADMINISTRATIVE & NATIONAL POLICY **REQUIREMENTS**, Section 4.

## ii. Commercial Items (Technical Data and Computer Software)

Proposers requesting a procurement contract must list all commercial technical data and commercial computer software that may be included in any noncommercial deliverables contemplated under the research project and assert any applicable restrictions on the Government's use of such commercial technical data and/or computer software. In the event a proposer does not submit the list, the Government will assume there are no restrictions on the Government's use of such commercial items. The Government may use the list during the evaluation process to evaluate the impact of any identified restrictions and may request additional information from the proposer to evaluate the proposer's assertions. Failure to provide full information may result in a determination that the proposal is non-conforming. A template for complying with this request is provided in Attachment G: PROPOSAL TEMPLATE VOLUME 3: ADMINISTRATIVE & NATIONAL POLICY REQUIREMENTS, Section 4.

## d. Other Types of Awards

Proposers requesting an award instrument other than a procurement contract shall follow the applicable rules and regulations governing those award instruments, but in all cases should appropriately identify any potential restrictions on the Government's use of any intellectual property contemplated under those award instruments. This includes both noncommercial items and commercial items. The Government may use the list as part of the evaluation process to

assess the impact of any identified restrictions and may request additional information from the proposer, to evaluate the proposer's assertions. Failure to provide full information may result in a determination that the proposal is non-conforming. A template for complying with this request is provided in Attachment G: PROPOSAL TEMPLATE VOLUME 3: ADMINISTRATIVE & NATIONAL POLICY REQUIREMENTS, Section 4.

## 5. Program-generated Data

Data are increasingly the key product of research and engineering endeavors. To ensure the reproducibility of results and access to source data for future research, awardees will be required to maintain and deliver any data generated during award performance ("program-generated data") that is needed to accomplish these goals. Awardees shall be expected to document both the proprietary and non-proprietary products of their research to ensure the retention and potential reusability of this information. This may include:

- Raw unprocessed data, software source code and executables, build scripts, process sequence, programmatic communication and other collaboration activities
- Data sets: rarified, experimental, test and measurement data
- Design of experiments and simulations
- Models or simulations (computational or mathematical)
- Recordings of various physical phenomena (including images, videos, sensor data, etc.)
- Access to and use of institutional, organizational or scientific community repositories and archives

When possible, DARPA may share some or all of the program-generated data with the broader research community as open data (with permission to access, reuse, and redistribute under appropriate licensing terms where required) to the extent permitted by applicable law and regulations (e.g., privacy, security, rights in data, and export control). DARPA plans to enable reproducibility of results through data sharing and to establish (or contribute to) digital collections that can advance this and other scientific fields.

## 6. Human Subjects Research (HSR)/Animal Use

Proposers that anticipate involving human subjects or animals in the proposed research must comply with the approval procedures detailed at <u>http://www.darpa.mil/work-with-us/additional-baa</u>, to include providing the information specified therein as required for proposal submission.

## 7. Electronic Invoicing and Payments

Awardees will be required to submit invoices for payment electronically via Wide Area Work Flow (WAWF), accessed through the Procurement Integrated Enterprise Environment at <a href="https://piee.eb.mil/">https://piee.eb.mil/</a>, unless an exception applies. Registration in WAWF is required prior to any award under this BAA.

## 8. Electronic and Information Technology

All electronic and information technology acquired or created through this BAA must satisfy the accessibility requirements of Section 508 of the Rehabilitation Act (29 U.S.C. § 749d) and FAR

- 39.2.
- **9.** Disclosure of Information and Compliance with Safeguarding Covered Defense Information Controls

The following provisions and clause apply to all solicitations and contracts; however, the definition of "controlled technical information" clearly exempts work considered fundamental research and therefore, even though included in the contract, will not apply if the work is fundamental research.

DFARS 252.204-7000, "Disclosure of Information"

DFARS 252.204-7008, "Compliance with Safeguarding Covered Defense Information Controls"

DFARS 252.204-7012, "Safeguarding Covered Defense Information and Cyber Incident Reporting"

The full text of the above solicitation provision and contract clauses can be found at <u>http://www.darpa.mil/work-with-us/additional-baa#NPRPAC</u>.

Compliance with the above requirements includes the mandate for proposers to implement the security requirements specified by National Institute of Standards and Technology (NIST) Special Publication (SP) 800-171, "Protecting Controlled Unclassified Information in Nonfederal Information Systems and Organizations" (see

https://nvlpubs.nist.gov/nistpubs/SpecialPublications/NIST.SP.800-171r2.pdf) and DoDI 8582.01 that are in effect at the time the solicitation is issued.

For awards where the work is considered fundamental research, the contractor will not have to implement the aforementioned requirements and safeguards. However, should the nature of the work change during performance of the award, work not considered fundamental research will be subject to these requirements.

## C. Reporting

## 1. Technical and Financial Reports

The number and types of technical and financial reports required under the award will be specified in the award document and may include monthly financial reports, monthly technical reports and/or a yearly status summary. A final report that summarizes the project and tasks will be required at the conclusion of the performance period for the award. The reports shall be prepared and submitted in accordance with the procedures contained in the award document.

## 2. Patent Reports and Notifications

All resultant awards will contain a mandatory requirement for patent reports and notifications to be submitted electronically through i-Edison (<u>https://www.nist.gov/iedison</u>).

## VII. Agency Contacts

DARPA will use email for all technical and administrative correspondence regarding this solicitation.

• Technical POC: Gregory Witkop, Program Manager, DARPA/DSO

- BAA Email: <u>STRENGTHEN@darpa.mil</u>
- BAA Mailing Address:

DARPA/DSO ATTN: HR001123S0016 675 North Randolph Street Arlington, VA 22203-2114

• DARPA/DSO Opportunities Website: <u>http://www.darpa.mil/work-with-us/opportunities</u>

For information concerning agency level protests see <u>http://www.darpa.mil/work-with-us/additional-baa#NPRPAC</u>.

#### VIII. Other Information

In order to ensure that U.S. scientific and engineering students will be able to continue to make strategic technological advances, DARPA is committed to supporting the work and study of Ph.D students and post-doctoral researchers that began work under a DARPA-funded program awarded through an assistance instrument. Stable and predictable federal funding enables these students to continue their scientific and engineering careers.

To that end, should a DARPA funded program (awarded through a grant or cooperative agreement with a university or a Research Other Transaction pursuant to 10 U.S.C. § 4021 where the university is a participant) end before the negotiated period of performance, DARPA will continue to fund, for no more than two semesters (or equivalent), stipend costs to Ph.D students and/or post-doctoral researchers. The stipend amount will be determined at the time of award based on the costs included for such participants in the University's original proposal. Universities are expected to make reasonable efforts to find alternative research opportunities for these participants before stipend funding is provided in this situation. This additional funding will not be provided in cases where an assistance award option is not exercised or any other scenario in which the University was aware at the time of award that the period of performance might not continue after a designated programmatic decision (i.e. a down-selection or inclusion of a subsequent programmatic phase).

## A. Proposers Day

The STRENGTHEN Proposers Day will be held on November 18, 2022 at the Executive Conference Center, Strategic Analysis, Inc. (4075 Wilson Blvd, Arlington, VA, 22203). The event will be webcast for those who would like to participate remotely. Advance registration is required for both the physical meeting and for viewing the webcast. See DARPA-SN-23-21 posted at <u>https://sam.gov/</u> for all details. Participation in the STRENGTHEN Proposers Day or viewing the webcast is voluntary and is not required to propose to this solicitation.

## B. Frequently Asked Questions (FAQs)

Administrative, technical, and contractual questions should be emailed to <u>STRENGTHEN@darpa.mil</u>. All questions must be in English and must include the name, email address, and the telephone number of a point of contact.

DARPA will attempt to answer questions in a timely manner; however, questions submitted

within 10 days of the proposal due date may not be answered. DARPA will post an FAQ list at: <u>http://www.darpa.mil/work-with-us/opportunities.</u> The list will be updated on an ongoing basis until the BAA expiration date as stated in Part I.

## C. Collaborative Efforts/Teaming

DARPA highly encourages teaming before proposal submission and will facilitate the formation of teams with the necessary expertise. Potential proposers may choose to participate in either, none, or both of the following options:

- 1. Attendee List (publicly available): Participant contact information (name, organization, email address) will be included on a STRENGTHEN Proposers Day Attendee List published on the DSO Opportunities website. The registration website will ask registrants to indicate whether they approve publication of their contact information.
- 2. Proposer Profile List (limited distribution): Interested parties will submit a one-page profile consisting of their contact information (name, organization, email, telephone number, mailing address, and, if applicable, organization website), a brief description of their technical competencies, and, if applicable, their desired expertise from other teams/organizations. All profiles must be emailed to <u>STRENGTHEN@darpa.mil</u> no later than 4 p.m. November 22, 2022. Following the deadline, the consolidated teaming profiles will be sent via email to the proposers who submitted a valid profile. Specific content, communications, networking, and team formation are the sole responsibility of the participants. Neither DARPA nor the DoD endorses the information and organizations contained in the consolidated teaming profile document, nor does DARPA or the DoD exercise any responsibility for improper dissemination of the teaming profiles. Teams need not be finalized at the time of abstract submission.