HR001125S0014
CoasterChase
Questions and Answers (Q&A)

Version 1 – 7/11/2025

General Information

1. **Has the Broad Agency Announcement (BAA) been published? Where is it posted?**
   A: Yes, it was published on 6/26/2025, and can be found at this the URL below:
   https://sam.gov/opp/82431f9c8fb14f73bfd8202a06391a03/view

2. **Will the Proposers Day slides be posted online?**
   A: Yes, information provided during the Proposers Day has been made available on the CoasterChase program page:
   https://www.darpa.mil/research/programs/coasterchase

3. **Is Dr. Irazoqui available for a call or meeting to discuss how our technology may align with the program?**
   A: In the interest of fairness to all interest parties, as Dr. Irazoqui will not have the availability in his schedule to honor all requests, we will not be scheduling and program-related calls or meetings. The best way to receive feedback on an approach is through the submission of a proposal abstract prior to the deadline specified in the BAA. The BAA describes the program, including metrics, in detail. Specific questions may be submitted by email to CoasterChase@darpa.mil. Proposers should be aware that submitted questions and answers may be published on a Q&A page, with revisions to remove proprietary information.

4. **Is teaming required? At which point should we form teams?**
   A: While teaming is not required, it is strongly encouraged to provide the expertise and capabilities needed to achieve the CoasterChase program goals. Proposing teams should have a plan in place for managing team interactions and future technology transitions and should be formed at the proposal abstract phase.

5. **Does DARPA prefer a specific team composition regarding type/size of organization, etc.?**
   A: There is no specific preference. Proposers are encouraged to form teams based on the team's ability to address the goals of Phase 1 and 2.

6. **Can individuals be part of multiple proposals under this solicitation, or are there any restrictions regarding team member overlap across different submissions?**
   A: Yes. Teams can be subcontractors on multiple efforts. However, if chosen for multiple awards, a clear path will be established to ensure no conflicts are present between the efforts. Proposers who are subcontractors on multiple teams should be cognizant of the distribution of the level of effort across multiple awards and will be required to ensure that DARPA is only charged once for any potential duplicate tasking.

7. **Will FFRDCs be eligible as performers for CoasterChase?**
   A: UARCs and FFRDCs are highly discouraged from proposing against this solicitation as award to a UARC or FFRDC will only be made by exception. UARCs and FFRDCs interested in this solicitation, either as a prime or a subcontractor, should contact the Agency Point of Contact (POC) listed in the Overview section

prior to the proposal (or abstract) due date to discuss potential participation as part of the government team or eligibility as a technical performer.

8. **Are there opportunities for independent verification and validation (IV&V) support for CoasterChase?**
A: No, CoasterChase is not soliciting for IV&V support at this time.

9. **Is it possible and likely that foreign nationals working at a foreign university (EU) can succeed in an application? (e.g., for NIH R01 grants it's not technically impossible, but in practice it basically is)**
A: Yes. As stated in Section IV of the BAA, "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."

Contracting and Cost

10. **How much funding is available for the CoasterChase program? What is the expected size of an award? Approximately how many projects is DARPA planning to fund?**
A: DARPA has approximately $25M total for performer awards and anticipates making multiple awards. DARPA has not predetermined individual award amounts. Proposers are required to provide a well-justified budget that covers the scope of the proposed work with tasks described and budgets requested to meet the CoasterChase program objectives. Budgets will be examined in detail for appropriateness. If the proposal is selected for award, a Government contract officer will negotiate the terms of the award – a Procurement Contract, a Cooperative Agreement, an Other Transaction Agreement for Research (OT-R), or an Other Transaction Agreement for Prototype (OT-P). During this negotiation, every aspect of the proposed work plan and cost proposal will be reviewed. Please follow all instructions and use all templates or attachments provided with HR001125S0014.

11. **Since Phase 2 is optional, should the cost proposal include only the Phase 1 (12-month) budget, or both Phase 1 and Phase 2?**
A: Both Phase 1 and Phase 2.

12. **Can DARPA partially fund a proposal?**
A: Yes, DARPA reserves the right to fully or partially fund a proposal.

13. **Are computing equipment costs allowed?**
A: Yes, and like other equipment costs, the purchase of specific computers or computational services will need to be supported by the requirements of the proposed work.

Program Scope & Structure

14. **Are Functional Areas 1 and 2 equally important?**
A: Yes.

15. **Does progress towards a milestone/ deliverable in one functional area (FA) impact continuation of effort in the other FA (i.e., if a high-risk approach fails), will other efforts from the same performing team potentially be cut?**
A: As stated in CoasterChase BAA Section 1, "Proposed research should investigate innovative approaches that **enable revolutionary advances** in enteric neuromodulation and sensing, ingestible electronics, and modulation of the stress response. Specifically excluded is research that primarily results in evolutionary

improvements to the existing state of practice." Please propose approaches to achieve the CoasterChase goals and milestones, and where a particular approach is highly risky, you should consider and propose mitigations to address the risk.

16. **Are there any expected milestones during which a performer will work with a government team for replication or independent validation?**
A: No.

17. **Will the program elucidate the effect of the intervention on the microbial community of the intestine?**
A: CoasterChase does not currently require (or forbid) microbial sampling.

18. **Are the following approaches to study change in the enteric nervous system (ENS) considered responsive to the CoasterChase BAA: 1) diet/nutrition/microbiome-based, 2) drugs that block receptor to affect NPY or targeting ENS, 3) gene editing tools?**
A: No.

19. **Does CoasterChase assume that cortisol is the only measure of stress?**
A: No. Additional biomarkers or measures of sensing stress may be proposed with appropriate justification.

20. **Measuring cortisol in the intestine is difficult, is it required?**
A: Measuring cortisol-related (but not necessarily cortisol directly) stress biomarkers from the intestine is required. Additional biomarkers or paradigms for stress detection may be considered as well, given appropriate justification.

21. **Would it be okay to sense cortisol externally (i.e., through a patch)?**
A: Initially, sensing cortisol (and/or other biomarkers) externally as a sampling method throughout stimulation may be considered with appropriate justification; however, sensing cortisol externally may not replace the sensing component that will form part of the ingestible platform.

22. **Does the stress/performance surrogate have to be endocrine cortisol-related, or can other plausible targets (i.e., neuroinflammation/immune activation) be allowable?**
A: The primary stress surrogate must be cortisol-related; however, additional targets may be allowable with justification.

23. **Would delivery of a small molecule to sensitize target neuron populations to electrical or mechanical stimulation (but not directly increase NPY production) be out of scope?**
A: Yes.

24. **Will selected CoasterChase performer teams retain intellectual property rights?**
A: The Government expects Government Purpose Rights (GPR) for the technology developed under the CoasterChase program and is open to flexible intellectual property (IP) proposals from performers that are advantageous to the Government (See Section 16 of BAA Attachment C for additional information).

25. **Will selected CoasterChase performer teams be allowed to publish the results generated under CoasterChase? Are there any limitations to publication of results?**
A: For university performers, DARPA expects the work performed under this award to be fundamental research, and it is, therefore, not subject to publication restrictions. Papers resulting from unclassified

contracted fundamental research are exempt from prepublication controls and requirements, pursuant to DoD Instruction 5230.27

For industry performers, DARPA expects that the work performed under this program will not be considered fundamental research. The U.S. Department of Defense (DoD) mandates all official DoD unclassified information that pertains to military matters, national security issues, or subjects of significant concern to the Department receive appropriate scrutiny before release to the public. As part of fulfilling this mandate, DARPA requires all DARPA-related information intended for unlimited public release to undergo reviews for technical accuracy, security and policy compliance, and adherence to overall quality standards. These reviews help DARPA offer accurate and timely information to the public, Congress and other key stakeholders, which in turn improves overall understanding of the valuable contributions DARPA and its performers provide to national security.

26. **After the CoasterChase selection process, will you publish the list of selected teams?**
A: While DARPA does not publish lists of selected teams for its programs, there are several places to find DARPA award information, including DARPA's website (especially the "news" section).

Abstracts and Proposals

27. **Is submitting an abstract required? What is the advantage of submitting an abstract? Does the abstract need to match the full proposal submitted?**
A: Proposers are strongly encouraged, but not required, to submit an abstract. DARPA will provide feedback for each abstract submitted. DARPA will attempt to respond to abstracts with a statement indicating whether DARPA is interested in the proposed idea. Regardless of DARPA's response to an abstract, proposers may submit a full proposal. DARPA will review all full proposals submitted using the published evaluation criteria and without regard to any comments resulting from the review of an abstract. Proposers should endeavor to follow the constructive feedback provided following abstract review. Finally, DARPA understands that final concepts and team make-up may change from abstract phase to final proposal as the technical approach is solidified. Please refer to Section 4 in the Program Solicitation for information on abstracts and Section 5 for information on full proposals.

28. **Can a proposal abstract be three pages in length if all the relevant points are addressed?**
A: Yes. There is no minimum page length requirement for proposal abstracts.

29. **Can multiple abstracts be submitted? For example, if we have two strategies to solve this problem can we submit two different abstracts for review?**
A: Yes.

30. **When will we receive the responses to the abstracts?**
A: Depending on the number of abstracts received, DARPA's goal is to evaluate all submitted abstracts and provide feedback by July 30.

31. **What is the page limit for the full proposal?**
A: There is a 20-page limit for the main body of the proposal. However, certain components of the proposal will not count as part of that page limit. Please read the instructions in BAA Attachment C for complete requirements.

32. Does Phase 2 need to be addressed in the proposal narrative and technical plan?
A: Yes.

33. Should the contract research organizations (CROs) involved in the proposal be identified in advance for DARPA approval?
A: Yes, for multiple reasons. DARPA will be evaluating proposal abstracts and full proposals for relevant qualifications. Proposing teams should demonstrate the ability to meet the technical goals of the program, provide examples of past performance or projects in the relevant technical domains (i.e., both FA1 and FA2), and demonstrate capability to navigate integration and animal research challenges anticipated in Phases 1 and 2.The BAA Attachment E. Cost Spreadsheet must be completed and submitted as part of the full proposal, including identification of Subcontractors and Consultants.

34. Who will conduct an expert review of the proposals?
A: Reviewers are Government employees who independently review every assigned conforming proposal received in response to a BAA or RA in accordance with the evaluation criteria. Reviewers may be DARPA Program Managers or qualified personnel from other DoD organizations and Government agencies who are deemed proficient in the pertinent technical area(s) of the solicitation.

35. What if a proposal superficially overlaps in methodology, platform design and fabrication, etc. with another proposal?
A: Recognizing that the CoasterChase requirements constrain the trade space for research, some overlap is possible. DARPA will not evaluate abstracts and full proposals against each other during the scientific review process but will evaluate the abstracts and full proposals on their own merit to determine how well they meet the criteria stated in the BAA.

Animal Subject Research (ASR)

36. What does DARPA consider to be a large animal model? Are the required large animal models required to investigate efficacy or safety or both?
A: A large animal model typically refers to non-rodent mammals. Proposals should not suggest non-human primates, cats, or dogs. The required large animal models should be used for both efficacy and safety studies.

37. Are the Phase 1 in vivo experiments required to use large animal models?
A: No.

38. Are rodent studies appropriate as part of FA1, Phase 1 or are only large animal studies appropriate? Can you propose multiple animal models in the same effort?
A: Data supporting the fulfillment of milestones and metrics in Phase 1 may be from rodent models; however, data supporting the fulfillment of milestones and metrics in Phase 2 must be from large animal models. Multiple animal models may be proposed in the same effort with the inclusion of justification. IACUC and ACURO protocol approval must be obtained for all animal subject research, including protocol development work.

39. Will IACUC protocols need to be approved / in progress at the time of Award Notification?
A: No; however, due to the time required for ACURO approval (2-3 months), submitting IACUC-approved protocols to ACURO after Award Notification and during contract negotiation (~90 days) is highly recommended.

Device Development

40. **Must the device maintain the capsule form factor after deployment in the small intestine?**
    A: No.

41. **Will the devices support electronics so that a model can be deployed on the device? Or support communication to a secure cloud service?**
    A: Devices should support local deployment.

42. **Is it required for the entire device to be ingestible? For example, what if sufficient electrical or mechanical energy could be applied with a combination of external and internal devices?**
    A: The entire device must be ingestible.

43. **Are there any size and, importantly, shape restrictions to the ingestible devices?**
    A: There are metrics for the diameter and weight of the ingestible platform (see Table 4, Item 22). There are no specific restrictions outside of these metrics.

44. **Could two concurrent devices be utilized together (i.e., sense and stimulate working in tandem)?**
    A: Yes, in Phase 1. Initially, sensing and stimulating can occur on two different platforms. In Phase 2, the integration of these two concurrent devices is a milestone.

45. **Is it possible to use multiple devices ingested sequentially to extend the sampling/intervention window or are you expecting a single device to be ingested and anchored for the entire 5-day intervention window that is mandated?**
    A: No. The final platform must be a single device.

46. **Must the final integrated device combine both proposed stimulation modalities -in closed loop- or only the successful modality(ies)?**
    A: The final integrated platform should have the ability to combine both stimulation modalities, even if it does not end up using both to achieve the program metrics.

47. **It's clear from the BAA that the ingestible device must support onboard, in-situ sensing. Are wearable sensors in scope (sweat, saliva), for example to provide additional monitoring or calibration functions?**
    A: Wearable sensors may be proposed in addition to the ingestible platform for initial monitoring or calibration functions, or validation and verification of the ingestible platform. These wearable sensors may not supplement or replace the ingestible device.

Other Technical

48. **Can you please define the terms used in your presentation and how each are within or outside scope: 1) inside the body, 2) outside the body, 3) wearable, 4) ingestible?**
    A: Descriptions of what is considered within scope for a CoasterChase proposal are included in DARPA's Broad Agency Announcement and proposal instructions.

49. **Can other target sites be utilized beyond S1 – e.g. stomach, direct to vagus nerve, etc.?**
    A: No.

50. **Any guidance for long term / chronic residency beyond the 5d metric?**
    A: There are no upper bounds on chronic residency for the platform, just the minimum bound of 5d.

51. **Is the second stimulation modality important, for example – if the first is successful, do we need to pursue/ integrate the second?**
    A: Yes.

52. **Are two electrical stimulation modalities (i.e., e-stim and temporal interference) acceptable?**
    A: Yes.

53. **Is specificity requirement tied to the neuronal type?**
    A: No.

54. **Is there an expected cadence for making sensor measurements or should sampling rates and schedule be based on dynamics of stimulation/response? Are you expecting continuous or intermittent sampling?**
    A: There is no specified cadence. The CoasterChase team expects sampling rates and schedule to be justified and informed using the data in FA1.