

NESD BAA FAQ

New FAQ entries since previous release are colored in blue.

Proposal Writing

1. Is Dr. Alvelda available for a call to discuss our proposed approach?

No. DARPA's policy is to ensure fairness to all proposers. The program manager is advised not to speak directly to potential proposers once the BAA has been published. Further, Dr. Alvelda will not be able to provide comments or feedback on an approach presented via e-mail. The BAA describes the program, including metrics, in detail. If you have specific questions or require clarification, please submit them by email to DARPA-BAA-16-09@darpa.mil. We have the discretion to re-word your question to remove proprietary information, but please be aware that your question, and its answer may be published on this public FAQ page.

2. How will the proposals be evaluated?

A team of government reviewers will evaluate applications based on the evaluation criteria described in DARPA-BAA-16-09. The reviewers all have scientific or technical expertise relevant to the goals of NESD, and may represent multiple government agencies, including FDA, NIH, NSF, NIST, and DoD research organizations. The review criteria are rank ordered, with the most important criterion being listed first in Section 5.1 "Evaluation Criteria".

3. Should I submit via DARPA's BAA website or grants.gov?

DARPA-BAA-16-09 allows for use of both methods. DARPA does not have a preference, though we have found fewer submission problems using DARPA's system. Please note, however, that proposals requesting cooperative agreements must be submitted via grants.gov or hardcopy. We encourage you to submit your proposal a few days ahead of the deadline.

Regardless of the submission mechanism, you should expect that DARPA will award NESD instruments as contracts, not grants.

4. Do page limits include table of contents, list of figures, and list of tables?

No. Please see Section 4.3 "Formatting Characteristics" for a description of the content encompassed by the page limits.

5. Do proposed personnel have to be US citizens?

No. We welcome the best ideas and research from any source. PIs, co-investigators, students, post-docs, employees, subcontractors, and institutions do not have to be US citizens or based in the US. All proposed and awarded work must comply with US laws and regulations, including animal and human subjects use.

6. Will abstracts receive feedback from DARPA? When?

Yes. The feedback will indicate specific suggestions for whether or not it is advisable to submit a full proposal (e.g. highly encouraged to submit, encouraged with significant changes, and discouraged). We will do our best to provide this feedback within 3 weeks of your abstract submission. You may still submit a proposal if you have received “discouraged” feedback, although these proposals are rarely funded. If you receive constructive feedback on how to improve your proposal, you should endeavor to follow this advice.

7. Do we have to submit a full cost break-down with our abstract, or is a ROM acceptable? Is there a template for the abstract?

Rough Order of Magnitude (ROM) cost estimates will suffice for the abstract phase. There is only limited formatting specified for the abstract submission, please read the instructions in section 4.3.1 “Proposal Abstract Format” of DARPA-BAA-16-09.

8. Will the proposer’s day slides be posted online?

Yes, the slides will be added to the registration website:
<http://www.sa-meetings.com/NESDProposersDay>

9. Can proposals list co-Principal Investigators [co-PIs]?

No. All proposals must list one lead PI serving as a point of contact for all contractual matters. Proposals may list co-investigators as key personnel.

10. I want to submit my proposal via grants.gov, but it does not allow me to attach editable documents, as specified in the BAA. How do I provide the Specification Spreadsheet (Attachment 3), the

Statement of Work (SOW, Attachment 4), and the summary slides (Attachment 1)?

Please submit these documents as a PDF file on grants.gov. The BAA coordinator (DARPA-BAA-16-09@darpa.mil) will follow up with you after your proposal is submitted to request the MS Excel, Word, and PowerPoint files via email.

11. Can I submit a similar/overlapping subcontract statement of work through more than one prime?

Yes. We encourage you to clearly indicate which portions of the proposed effort are common across all of your proposals, and which are unique. If DARPA chooses to fund more than one effort, we will examine the SOW and budget to ensure that your tasks are not duplicated.

12. Can an individual act as PI at Organization A and subcontractor at Organization B on a separate effort?

Yes. DARPA policy and Federal Acquisition Regulation (FAR) do not preclude proposer involvement with multiple efforts. The proposer must be very clear as to how hours will be charged in each proposed effort. Describe what safeguards are in place to ensure that time is not double billed.

13. How should videos be embedded into the proposal?

You are encouraged to provide videos of functional systems, simulations and experiments, as these can be quite compelling. Adobe Acrobat professional is recommended – instructions can be found at the Adobe website (<https://helpx.adobe.com/acrobat/using/rich-media.html>).

14. If my research is relevant in this field, but is not geared specifically to meet the NESD goals, is there a solicitation that I can respond to?

Yes. DARPA/BTO has an open solicitation (DARPA-BAA-15-35) for this purpose. Responses are being collected through 28 Apr 2016.

15. Where in the proposal should we include letters of support from advisors or unpaid collaborators?

Volume II, along with supporting documentation from other team members.

16. Are subcontractors required to complete the SOW template?

Proposers should submit one Statement of Work (SOW) that encompasses all the activities of the prime and all subcontractors. The numbering of tasks should be consistent across the SOW, Gantt Chart, Work Breakdown Structure (WBS), and Budget.

17. Can you clarify what level of detail is required for subcontractors?

All subcontractor proposal documentation must be prepared at the same level of detail as that required of the prime contractor.

18. Can DARPA partially fund a proposal?

Yes. DARPA reserves the right to fully fund or partially fund a proposal. More details can be found in Section 2, "Award Information".

19. How do you envision intellectual property cross-licensing to yield a product?

The BAA describes the government's IP assertions and requirements in Section 8.1, "Intellectual Property".

COST PROPOSAL

20. How important is the Cost Proposal?

The cost proposal is very important. Proposers who do not submit a well-constructed cost proposal may be considered non-responsive to DARPA-BAA-16-09. A well-prepared cost proposal is described in Section 4.4.2.2 "Volume II, Cost Proposal".

21. Is the budget template (attachment 2) mandatory?

No. Whether you choose to use this template or not, Section 4.4.2.2 “Volume II, Cost Proposal” encourages you to provide the level of detail exemplified in the template. You may find it easier to use the template than to create one from scratch.

22. If I choose to use Attachment 2, will it form the entirety of my cost proposal?

No. Although the template encompasses a large portion of what Section 4.4.2.2 “Volume II, Cost Proposal” requires, it does not include everything necessary for the cost proposal. Be certain to carefully review these sections to understand what is required in the cost proposal.

23. How can I access the tutorial videos for Attachment 2?

We have created the following tutorial videos to assist you in completing Attachment 2 for the NESD BAA:

Part I: Example Budget: <http://youtu.be/Np-OHcLnfdA>

Part II: Editing and Customizing the Blank Budget Template: <http://youtu.be/Obr7H8bYIG4>

You will notice that these videos were made specifically for the HAPTIX BAA (DARPA-BAA-14-30). Although the HAPTIX BAA is mentioned, the instructions are also applicable to the NESD BAA.

24. Please clarify the cell color legend that can be found on numerous tabs in Attachment 2.

You can edit any cell (data or formula) as necessary to fit the template to the structure of your specific project. The cell color legend is included to show you which cells contain formulas (white cells – which can be edited) and which cells are used for data entry (grey cells).

25. I am not very familiar with how to use MS Excel. What concepts are key to understand in order to use the template?

Although the template can appear very detailed and complex, it is compiled using very simple MS excel concepts. It is necessary to understand the formulas for basic arithmetic functions, how to link data within and across tabs, and absolute reference. A helpful tutorial on absolute reference can be accessed through the following link: <http://youtu.be/NmVMjQzseLA>.

26. Is there a recommended total cost?

No. DARPA has not pre-determined award amounts. Proposers are required to provide a well-justified budget that is appropriate for the scope of the proposed work. Your cost should be based upon how much money is required to perform the tasks you feel are necessary to meet the objectives in the Technical Areas described in Section 1 of DARPA-BAA-16-09. Proposals must be fiscally conservative and will be scrutinized for unnecessary or inflated expenses.

If your proposal is selected to be awarded, then a government contract office will negotiate the terms of the contract. During this negotiation phase, every aspect of your statement of work and cost proposal will be negotiated. Please ensure that you have followed all of the instructions in DARPA-BAA-16-09, including the required checklist in Appendix 1. This will enable the government contract office to expedite negotiations.

27. What is cost realism?

One of the review criteria is cost realism, and it is described in Section 5.1.3. Reviewers will evaluate salaries, equipment, supplies, travel, etc. There is no explicit salary cap. During contract negotiations, our contract officer will question the cost reasonableness of every item in the budget. Be sure to provide detailed quotes and justifications for your proposed expenses.

28. Do I have to provide a budget for all three phases? How can I know what my expenses will be four years from now?

Yes. Provide complete budgets for all three phases. All phases should contain the same level of detail that is requested in Section 4.4.2.2 “Volume II, Cost Proposal”. Put together a plan that you feel will be a likely course for the entire proposed effort. Contracts will be negotiated to award Phase I, and will pre-negotiate options for the subsequent Phase(s). These options will be executed (i.e. turned on) if DARPA is satisfied with your results and if DARPA has available funds for your effort. By negotiating these options within the scope of the DARPA-BAA-16-09, we can avoid substantial delays and problems that might arise from beginning negotiation on subsequent phases at a later date.

There will be opportunities to revise contracts at the awarding of each option. All parties will find it reasonable to update their expected costs, scope, and deliverables based on the progression of NESD. These re-negotiations will require the concurrence of all parties and will not be unilateral.

29. What is entailed in a PI Meeting?

Section 6.2.1, “Meeting and Travel Requirements” describes PI Meetings. Briefly, PIs are expected to meet with the Program Manager and the other PIs awarded under this program. This will occur roughly twice per year. It is expected that PIs will freely share their research results with each other and the Program Manager.

30. Should I budget for collaboration with parties not included in the proposed team?

Yes. If you plan to support work performed by another team (e.g. an informal collaboration with another group working in a different technical area), then indicate such effort as a separate task or sub-task, with associated costs itemized for those tasks and subtasks.

31. How can we budget for travel? We don't know where DARPA meetings will be located.

You should plan on sending key personnel to at least two PI meetings per year at a major US city, as well as other mission-relevant events. Be sure to justify the relevance of the non-DARPA events. A common practice is to assume that the PI meeting location will alternate between the west and east coasts (e.g. California and Washington, DC). Costs can be estimated using standard lodging and per diem rates posted at <http://www.gsa.gov/perdiem>. There will be no registration fee for DARPA-sponsored meetings.

32. Should my budget be only for direct costs?

No. Please be sure to include all Other Direct Costs (ODCs), indirect costs, G&A, and other indirect expenses that will be charged to the government should you be selected. This includes surgical and other patient costs that you expect will not be reimbursed by insurers.

33. Does DARPA have a plan to divide the funding among various approaches (e.g. electrical, optical, etc.)?

As per page 3 of the BAA, "Multiple awards are anticipated". DARPA is agnostic to the approach taken and will make decisions based on the merit of the approach. A diversity of approaches could be beneficial to DARPA's portfolio of investments and this could be one of many factors that influence award decisions.

34. Can an organization be a principal investigator on one proposal and in a separate submission a subcontractor/sub-prime?

Yes, see Questions 11 and 12 above.

35. Can government entities submit proposals?

Yes, government entities can submit proposals if they meet certain criteria specified in BAA section 3.1.1.

36. Is an abstract submission required?

No, but submitting an abstract is advised. It is the only channel that a proposer can use to get targeted proposal-specific feedback before the final submission.

37. How does DARPA protect the proprietary data in our proposal?

DARPA takes your IP rights very seriously, and protects them with the full weight of the federal government. We are prohibited from releasing any information about your proposal, subject to criminal repercussions. We need you to provide a clear picture of your approach in order to adequately evaluate your proposal and encourage you to feel comfortable sharing proprietary data in your proposal. Should you be selected for funding, any release of proprietary information is at the discretion of your organization.

Technical Areas 1 and 2

38. Must I respond to all of the NESD goals?

No, however, “Proposals are strongly encouraged to address all NESD program requirements.”

We encourage you to only submit responses to the technical areas that strongly align with your strengths. It is acceptable to propose work that only addresses a portion of the program objectives. However, if you feel your research interests are too narrow (but deep) to substantially contribute to a NESD system, we strongly encourage you to consider teaming with others.

Furthermore, we encourage you to describe how your team will conduct or work with other performers to accomplish the overall NESD goals. At a minimum, you must address the constraints/requirements your approach places on other teams’ solutions, along with any required contributions from other partners necessary to successfully implement your approach in pursuit of the totality of the NESD program goals.

39. I’m confused by the million, hundred thousand, and thousand channel requirements. Can you explain further, and are these “aspirational” goals or literal goals of the program?

The metrics posted in the BAA are literal – we believe that it will be very difficult, but ultimately possible, to build a NESD system that meets the specifications listed in Table 1. The wording in the numerical requirements tables was very carefully refined to offer important technical flexibility despite the aggressive goals. Pay attention to every detail. For example:

The final NESD system must be able to read from at least 1,000,000 individual channels of single-neuron information (e.g. action potential), (but there is no algorithmic timing requirement listed in this section.) these million do not have to be read out in real-time. In other words, it’s not necessary to track action potential-scale temporal information from all million neurons simultaneously. That aspect of the READ requirement may be a proposer-specified metric.

The final NESD system must be able to WRITE to 100,000 independent channels of neural information, but note that the specific precision is omitted, and may be part of a proposer-specified metric. A subset of the 100,000 must be writable in real-time. In other words, the temporal accuracy of stimulation must be highly controllable.

The final NESD system must be able to read and write from 1,000 neurons simultaneously and in real-time. In other words, every one of the thousand neurons must be measured and stimuable with enough temporal precision to provide accurate reconstruction of neural activity and generation of naturalistic sensory response and demonstrated behavior.

While we desire for all three of these capabilities to be embodied in a single NESD device, you may develop up to three (one per capability) discrete systems. No system may exceed 1 cm³ in volume.

40. Will teaming with other researchers be required?

All performers will be expected to build complete interoperable systems to achieve the goals of the program. Please read “System Transition” on page 8. It may be difficult for any single investigator or small entity to muster state-of-the-art technical contributions across the entire range of diverse disciplines necessary to build a functional NESD system suitable for use in humans, much less comply with the rigorous quality processes required to attain an IDE. You are encouraged to build a capable and diverse team in order to develop a comprehensive proposal.

41. What is the timeline for this program?

Please see Figure 1, “NESD Program Plan and Milestones” on page 12.

Proposal abstracts are due on February 25, 2016. Full proposals are due on April 14, 2016. Proposers are encouraged to submit full proposals before the submission deadline to avoid last-minute issues.

DARPA will select awards and notify the awardees as soon as possible. DARPA does not speculate or make any promises on this notification date, or the duration of the contracting process. We are hopeful that grants or contracts will be awarded as early as November 2016, but the process may extend into December 2016 or later depending on contracting and performer responsiveness to the contract officer’s requests.

We expect to hold a kick-off meeting for the NESD program in November 2016. At the kick-off meeting, we expect all performers to elaborate upon their plans and begin working together towards the overall NESD goals.

42. Should we take a conservative approach in some areas, in order to lower risk?

No. As per page 6, proposals wherein significant or fundamental aspects lag state-of-the-art approaches and technologies may be considered non-conforming. Nonconforming proposals may be rejected without review.

43. Will you accept proposals using non-invasive interfaces?

Yes, provided that they are technically, and operationally likely to meet all of the NESD program goals as laid out in the BAA, specifically Table 1, “NESD Target System Performance Metrics” on page 7.

44. Will you accept proposals that involve high-risk techniques, such as gene therapy?

Yes, provided that they are likely to meet all of the NESD program goals as laid out in the BAA, specifically “Regulatory Plans and Execution” on page 7 of the BAA, and include feasible approaches and appropriate strategies and milestones to mitigate those risks. The BAA requires direct engagement with the FDA early in the program through pre-submission discussions to gain insight into requirements for the ultimate IDE certification. Your proposal should describe potential fall-back approaches in the event of insurmountable bottlenecks or delays.

45. Will you accept proposals that interface with the peripheral nervous system or spinal cord?

No. This solicitation is focused only on interfaces with regions of the human sensory cortex.

46. What volume of tissue must the NESD system interact with?

Table 1, “NESD Target System Performance Metrics” on page 7 specifies access to a cortical region of interest of 2 cm². The depth of tissue depends on the target therapeutic neural interface application and its associated target sensory cortical region(s) that you specify. The ultimate details of how channel count and neural precision levels are distributed across the proposer-selected cortical areas of interest, the shape and distribution of the cortical area (i.e. whether or not it is contiguous) should be driven by the specific therapeutic application chosen in the proposal.

47. The number of neurons under a 2 cm² region of interest (Table 1, page 7) is greater than the NESD-required number of neural channels.

Yes. We expect your proposed system to have the ability to interact with an appropriate subset of these neurons. Your approach should be able to target the specific neurons of interest required to accomplish your therapeutic application and benefit.

48. Are there any restrictions on the device form factor other than the volume constraint?

No, but you should be mindful that the proposed device must be designed to be implantable and there will be physiological constraints.

49. Are we limited to the visual or auditory cortex?

No. Page six of the BAA states, “Proposers are encouraged to focus on cortical sensory pathways where deterministic neural activity encoding and computation models are best understood and can most easily be tested against precise yet complex stimuli. DARPA strongly prefers applications that highlight the benefits and improved functionality enabled by the scale and precision afforded by the proposed NESD systems compared to the state of the art, and would not be possible without the proposed innovations.”

50. Is there a separate track for preclinical and translational development? That is, can the device take different forms for pre-clinical vs. translational?

No. The final IDE-approved NESD system is the objective of this program. There is no pre-clinical objective other than to support translational technology development.

51. Can we take an incremental approach to developing our system, i.e. can we demonstrate portions of the system early in the program independently of other portions of the system?

Yes, as long as you meet the overall goals of the program, and satisfy each of the intermediate milestones. Milestone 4 is a bench top demonstration.

52. Can you speak to the day-to-day execution of the NESD program? How do you want us to propose modeling, animal work, human subject testing, experiments, etc.?

No. We have provided the milestones and metrics in the BAA and want proposers to provide their own plan for achieving these milestones and metrics.

53. [Is there a device commercialization requirement?](#)

[No. The BAA only specifies that proposed teams must contain individuals with demonstrated experience bringing integrated medical products to market \(page 6 and Section 5.1.1\).](#)

54. Will DARPA consider relaxing the Phase III system volume requirements of $< 1 \text{ cm}^3$ if the device is recessed into the skull?

No. The specification incorporates the possibility that some solutions might involve recessed devices.

55. How important is product and user interface design to the NESD program?

NESD is driven by a combination of the performance specifications listed in the BAA, and the specific therapeutic application that you choose to address in your proposal. We encourage proposers to consider product design and patient needs to be important aspects of systems engineering. You may find this approach will help balance the tradeoffs between components in your system.

Guidance on design can be found at the following link:

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070627.htm>

56. How does the BAA identify which clinical applications are being targeted?

The BAA does not identify a clinical application. This is intentional. As stated on pages 5 and 6 of the BAA your proposal needs to define and justify an application that you feel can meet the objectives of the program.

Human Subjects

57. Can we start human trials before Phase 3?

Absolutely! As long as you have proper approvals, we would love to see some "early wins." Be sure to pay attention to the metrics and goals of NESD, Section 6.2.2 "Human Subjects Research", and "Ethical, Legal, and Societal Implications" on page 15.

58. I need help understanding the approval process for human use.

The BAA includes numerous footnotes linking to guidance documents. We encourage you to read these. The PI is responsible for ensuring that everything is in order. You may wish to hire a consultant or engage directly with your IRB prior to submission. You are not required to have IRB approval prior to submitting a proposal, but be prepared to work with your IRB immediately, should you be selected.

We are unable to provide funding for tasks that contains human use until after you have attained all of the necessary approvals. We strongly encourage you to separate out the task dependencies to ensure that human use tasks can be turned on as "options" once approval is granted. For example, equipment purchases and setup should be included as a separate task from the actual experiments where subjects use the equipment. Otherwise, DARPA will not be able to release the funds to purchase the equipment until the experimental protocol is approved.

59. Can we pay patients for their travel expenses and time?

Yes, if approved by your IRB and the secondary DoD IRB. The payment can't be an incentive or be seen as coercion.

60. Can we perform human subject testing outside the United States?

Yes. In addition to local requirements, all procedures related to human subjects testing must be approved by a DoD human subjects protection board, which follows similar rules to an US-based IRB. Milestone 12 of NESD is to attain approval from the United States Food and Drug Administration for an Investigational Device Exemption (US FDA IDE).

61. Will you accept proposals that do not include human use components, or those that focus primarily on animal model experiments?

No. Any proposed NESD system whose approach or scope fails to satisfy a major requirement, including that for ultimate demonstration in humans, may be considered non-conforming and risks not being reviewed. We recognize that in order to receive an IDE from the FDA, animal models may be required to demonstrate safety and/or efficacy, but any propose animal model experiments should be considered as specific and absolutely necessary stepping stones to achieve certification for human experiments as rapidly as possible, and not as research goals in and of themselves.

Additional Questions

To be added at a later date. We expect to update this FAQ weekly. Check <http://www.darpa.mil/work-with-us/opportunities> for updated posts.