

FDA Broad Agency Announcement Q&A Day

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- Take advantage of this virtual event and the opportunities provided to understand our mission, meet, and network with the attending FDA staff (to include Contracting, Program)**
- What is the purpose of this BAA?

The FDA solicits for advanced research and development proposals to support regulatory science and innovation. The FDA anticipates that research and development activities awarded under this BAA will serve to advance scientific knowledge to accomplish its mission to protect and promote the health of our nation.

The result of this process is that various proposals, based on scientific review and relevance, will be selected to be awarded contracts.



What is the difference between a contract and a grant?

- Federal Grants and Federal Contracts have significant differences. The government uses grants and cooperative agreements as a means of assisting researchers in developing research for the public good, whereas it uses contracts as a means of procuring a service for the benefit of the government. Grants are much more flexible than contracts. Typically in Federal Contracts, changes cannot easily be made to the scope of work or budget, whereas in grants these changes can usually be made with the governments approval. Failure to deliver under a Federal Contract can have potential consequences to the vendor , whereas in the case of a grant typically a final report explaining the outcome is sufficient.



- What is new for the 2023 FDA BAA from a contracting prospective?**
- This year a preference will be given to cost reimbursement, severable proposals vice firm fixed price, non severable proposals.

- Why the change in preference?**
- For research of the type that is generally awarded under the BAA announcements, a firm fixed price contract may not be the most optimal type of contract vehicle. A firm fixed priced vehicle requires defined deliverables or outcomes. By definition, research may not result in a deliverable or an expected outcome.



What about severability vs nonseverability?

- "Severable" describes an action that can be divided into two or more parts that are not necessarily dependent upon each other. "Non-severable" describes an action that cannot be divided into two or more parts without negatively effecting performance of the task.
- Whether a contract is for severable or nonseverable services affects how the agency may fund the contract; severable services contracts may be incrementally funded, while nonseverable services contracts must be fully funded at the time of the award of the contract.
- How does this potentially impact our proposals?
- A defined and detailed cost proposal will be required:



Applicable clauses are different for a cost reimbursement contract

- Beginning on page 64 of the BAA announcement, we give examples of the clauses that may be applicable to your proposal.
- Clauses will be tailored to each individual awarded contract, these are examples only, not an exhaustive list.

- Can we expect negotiations as a part of the contract award process?

The government will retain the right to negotiate with each offeror. It depends on a number of variables, but negotiations are always possible on BAA awards.

- How can we improve our chances if we aren't selected this year?

While the reasons vary from incomplete packages to limitations in funding and relevance to the research areas, you may always request to speak to the CO for specific feedback.



- What if we are new to this process, and/or a small business?**

- WELCOME! The FDA is happy you are here, and we value your potential partnership!**

- Talk to your Contracting Officer (That's me).**

- What can we do for you? Point you towards resources, answer general questions, clarify points of federal contracting complexity.**

- What am we prohibited from doing? Reviewing your proposal before submission, answering “what should I research” or “what are my chances” kinds of questions. Especially not “what are other people submitting” questions!**



- What constitutes “research” for this solicitation? Does education based on informing the public on one health considered appropriate?
- Applied research means the effort that (a) normally follows basic research, but may not be severable from the related basic research; (b) attempts to determine and exploit the potential of scientific discoveries or improvements in technology, materials, processes, methods, devices, or techniques; and (c) attempts to advance the state of the art. When being used by contractors in cost principle applications, this term does not include efforts whose principal aim is the design, development, or testing of specific items or services to be considered for sale; these efforts are within the definition of "development," given below.
- Development, as used in this part, means the systematic use of scientific and technical knowledge in the design, development, testing, or evaluation of a potential new product or service (or of an improvement in an existing product or service) to meet specific performance requirements or objectives. It includes the functions of design engineering, prototyping, and engineering testing; it excludes subcontracted technical effort that is for the sole purpose of developing an additional source for an existing product.



Questions on Contracting Matters?



THANK YOU FOR ATTENDING FDA Q&A Day



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