

2024 FDA BAA Day Q&A on November 14, 2024

Question	Answer
Will funding be the same as last year, or higher or lower?	Live answered
What is happening with the full proposals that were submitted last year but were not awarded because the FY24 funds ran out?	Live answered
What are the timelines for the BAAs?	Live answered
What are key components of strong concept papers?	Live answered
What has changed from last year relative to the proposal submission process?	Live answered
For the FY24 awards that were just announced, how many of those were new awards and how many were follow on funding (option years) to existing projects?	Live answered
Dr. Michele Lee: Regarding the user experience of devices for all populations, do you mean devices that are meant for therapeutic benefit, or does it also include DHT devices used to measuring outcomes of new therapies?	Both may be relevant. While the intent of that section was for devices meant for therapeutic benefit, I can also see how improving user experience for DHTs to measure outcomes of therapies in underrepresented populations can also be relevant to our Center's research priority of Advancing Health Equity
Typical \$ amount of MCMi / ORES projects?	Presented by Dr. Robert Orr on slide 19
When should we expect to hear back on concept proposals?	FDA recommendations for optional early concept papers will be notified on 12/16/2024
Is methodological work to improve the accuracy and speed of vaccine effectiveness evaluation using simulation and modern causal methods aligned with your priorities?	Live answered
When will the initial proposals be due? (apologies for the naive question)	Feb 24, 2025 11:59 pm EST

Can FDA employees apply for research funding through the BAA mechanism?	Any entity registered in SAM.gov can apply, though in this case we would want to check with the ethics office about possible conflicts of interest.
PFAS Dairy: Are you more interested in PFAS animal kinetics or mitigation strategies?	Live answered
Will you accept dairy sheep or goat if replication and site is an issue for cattle?	Live answered
I noticed in the PDF of funded proposals, that last year it didn't look like anything was funded in the BAA through OneHealth. Can you speak to what influence OneHealth had on last's years funding, and whether OneHealth is planning to independently select proposals by itself next cycle?	Live answered
Is there interest in contraception use/discontinuation?	Live answered
For Women's Health are you interested in improving communications and identifying misinformation to woman?	Yes, we are interested in improving health communications for women. As listed as priority area in our Research Roadmap, we are interested in any research focused on "developing, evaluating, and facilitating the awareness and use of tools and methods to foster the creation of easily accessible, clear, and useful information about FDA-regulated products used by women to help women and health care professionals make informed health-related decisions."
Are the areas presented today all the areas of interest this year?	All of the charge areas can be found in the BAA Announcement
Are concept paper and full proposal due on the same date?	Concept papers were due on Nov 8th, the full proposals are due Feb 24, 2025 11:59 pm EST
Is it okay to submit a full proposal with a concept paper attached now?	Yes you may submit any time before Feb 24, 2025 11:59 pm EST, but it will not be reviewed until after 24 Feb.
What is the timeline for folks to get a response from the FDA on the Optional Freestanding Concept Paper that were due on Nov. 8th?	Feedback will be sent out 12/16/2024

Wasn't the concept paper optional for Nov 8th deadline?	Yes that was an optional concept paper
More general question: If my research area seems relevant in the BAA Announcement but was not covered here, who should I contact to see if there is agency interest? In particular, we are interested in an area relevant to the CDER Office of New Drugs.	In such scenarios, submitting an optional early concept paper is the best approach. As the due date for submitting an optional early concept paper has passed, please send your query to FDABAA.fda.hhs.gov.
If you did not submit a concept paper can you still submit a full proposal?	Yes you can
What is the typical timeline and budget range funded?	Contracts usually run 1-5 years. The budget range varies greatly by center. You can find the awards from previous years on SAM.gov.
Thank you. Should the applications be single PI or are MPI applications ok too?	They can be either
Is there a difference between the three lack of funding types?	Live answered
Is there still time to submit the early concept paper? Seems like the deadline has passed?	The deadline has passed.
Where can we find the FDA priorities in order to submit an early concept or Stage One Package?	Please refer to the FY25 BAA announcement: https://sam.gov/opp/c3e35e83134c40e5b96dde9c65f5c23a/view
There have been limited funding of projects with social science/behavioral focus this past year. Do you anticipate similar trend this year?	Live answered
Can a person be on multiple applications?	Yes.
Please confirm, if you did not submit Optional Concept Paper but want to submit a full proposal, you still must include the 3 page concept paper as part of the full application?	Yes, that is correct. Any submission needs to include concept paper and full proposal
Dear FDA BAA team, Would it not be better to give this presentation before the deadline for early concept papers? Or, use a deadline after this presentation. Asking for future BAA contracts	We will take that under advisement for future BAA days. The SAM.gov posting that published the Nov 8th date was Oct 03 2024.
Is there a time frame for hearing about applications that are "pending"?	Live answered
Who reviews the concept proposals? Are the needs of the Centers/Offices that presented today given priority?	Live answered

Concept paper still required with full application?	That is correct. Please refer to the FY25 BAA announcement for further details: https://sam.gov/opp/c3e35e83134c40e5b96dde9c65f5c23a/view
If we were unable to submit a concept paper is there another way to get high-level feedback on an idea?	Live answered
When should we plan to receive first funding, so we can plan that in the proposals?	Contracts are typically awarded July - Sep each year for BAA's
Will the change in administration have an impact on BAA funding levels?	We will only have that answer when a budget is passed. We are currently operating under a continuing resolution
If an early concept paper was submitted with title page and table of contents. Will that count as part of the three page limit and therefore only one page of concept-paper content will be considered?	Live answered
If an early concept paper was submitted with title page and table of contents. Will that count as part of the three page limit and therefore only one page of concept-paper content will be considered?	If it is only the title page and table of contents, it will not be considered towards the 3 page limit. We recommend that you follow the template provided in attachment 4 of the BAA announcement.
Is it potential for BAA24 proposals in pending status that are severable to be still awarded with part? Given the \$39M already awarded, it is unclear if that includes potential pending proposals or could increase with pending proposals.	Live answered
What is the maximum funding for the PFAS in dairy cattle call? I cannot find it in the RFA	Similar in size to last year's minimum and maximum funding
The submission is via email right? Can you explain how is that related to SAM registration?	Live answered
Are there any rules regarding potential overlap with NIH funding?	Live answered
Is it possible for two institutes collaborately submit an application?	Live answered
For re-submission of last year FDA BAA, what will be the project starting date?	Live answered

Can federal employees be PIs on projects if their agency is registered in Sams? This would be a USDA Agricultural Research Service employee	Live answered
Why is it possible to submit the full proposal even if the early concept paper is rejected? Which is the rationale of that?	It would be the applicant's business decision to follow or not follow FDA's recommendation. If an optional early concept paper was submitted and FDA feedback was received, the applicant can submit a revised proposal as part of stage one application (includes concept paper and full proposal)
Can USDA scientists lead or be CoPIs in this call?	Live answered
Does the institution need to be registered with SAM or the individual PI	Live answered
Is it recommended that the proposed tasks are severable, so that it is possible to be funded partially?	Live answered
I missed the first part of the session, when the recording will be available?	Live answered
How will you let us know about the PFAS funding max?	Live answered
Can the budget of awarded multi-year contract be increased/amended in the future years?	Live answered
The budget says subcontracts need detailed budgets for 250k+ - is that direct costs or total costs? For one year or total project length?	Live answered
Are there any restrictions on the overhead?	Live answered
Can you tell us more about review process?	Live answered
If we are awaiting a funding decision what is your recommendation about when to resubmit. The response for our FY 24 project was positive but funding dependent. Should we resubmit now, or wait till Dec 6th?	Live answered
For FY2025, charge area IIIb1a, what is the anticipated funding for this priority area? \$250K or more?	Live answered
For volume I appendices, it asks for biographic sketches but then also calls them resumes. Are NIH biosketches sufficient? Are you looking for a biosketch *and* resume?	Live answered
Is there a policy on using live hyperlinks in proposal documents?	Live answered

What is the level of feedback provided on the concept proposals? Will we get feedback on the idea as well as the budget? Recommendations for applying the method to a different topic?	Live answered
A question about the review process. For proposals that target a specific Center, would the people from that Center invited to provide the feedback on the proposal?	Live answered
Can the proposal include both basic research and applied research?	Live answered
Re-submission of last year BAA proposal will go to review as well?	Yes, it will follow the same review process.