BAA Q&A Session- Tuesday, January 16, 2024

Number	Question	Answer
1	Will this session cover questions / resources available for completing the Appendix 7 - Cost Proposal template for BAA submissions?	If you would like to ask specific questions on the cost proposal, please do.
2	Hi! Would you be able to describe the Federal Portal and reporting submission processes that grantees will use if awarded funds? This is primarily in regard to the monthly (15th of each month) invoice/financial reporting requirements.	The invoicing requirements would be through the IPP portal. As far as financial reporting, that would be case-by-case through the individual contracts.
3	On pg. 75 of the 111-pg. overview, it states that Direct salaries are limited per HHSAR clause 352.231-70 Salary Rate Limitation. It sounds like we cannot use granted funds to pay the direct salary of an individual at a rate in excess of the Federal Executive Schedule Level II, which would be $212,000. Does this mean that a single staff person cannot be paid more than $212,000 annually for project activities? If their salary is higher than $212,000, is it ok for funds to be allocated towards a percentage of that total?	Please refer to question number 90
4	On page 15 of the notice, under the "Biographical sketches/Resumes/Roles and responsibilities" section there are instructions to provide "a list of the last three (3) government related contracts during the past three (3) years and all contracts currently being performed that are similar in nature to the BAA scope." Is this information to be provided for the offering company overall or only for the key personnel listed?	The preference would be for the offering entity to be able to do that. Again, if they are hiring the key personnel and the key personnel are the ones with the past performance, then that is acceptable

5	"Attachment 3: FY24 BAA Application Checklist" (starting on page 99 of the notice) implies that the statement of work (SOW) should be submitted as a standalone document. However, "Attachment 5: FY24 BAA Volume I Technical Proposal Template" indicates that the SOW should be included in the Appendix of the Technical Proposal. Including the SOW in the Appendix is also indicated in "Section B. Volume I – Technical Proposal Appendices". Could the FDA clarify if the SOW should be submitted as a stand-alone document or provided in the Technical Proposal Appendix? If it should be included in the Appendix, will it be counted against the Appendix's 20-page limit?	Because we didn't specify, that is acceptable. What I would say is that my preference, and this is definitely the way we will write it up next year. My preference is the SOW, even if it is listed in the main body of the proposals that it is also supplied as a stand-alone Word document. If it is applied more than once, obviously the secondary one would not count toward your page count. we can confirm that these are items that would not contribute to the page limit. One is a statement of work and the other would be the biographical sketches and resumes.
6	On page 78 of the notice, in section "Preparation of Volume II – Cost Proposal Appendices," it states that a template for the HHS Small Business Subcontracting Plan has been provided as a separate attachment to the announcement, however one is not posted on SAM.gov. Could the FDA please provide its desired template?	We do not have a template for this, and it is a business decision up to each large entity as to how they will subcontract.
7	For FDA BAA topics related to cancer clinical trials, would this research be OMB PRA exempt as other federal cancer research has been?	It would depend on the proposal's objectives and methods. PRA for each proposal will be handled on a case-by-case basis. Include 9-12 months in the proposal timeline for PRA approval.
8	Could the FDA clarify if subcontractor cost proposals, consultant agreements, vendor quotes, and other back-up documentation required in support of ODCs, materials/supplies, and other documentation required in support of pricing and rates should be included in the Cost Proposal Appendix or submitted as separate attachments? If these documents should be placed in the Appendix, can the FDA please confirm that they will not be counted against the 20-page limit?	It does not count toward the page limit
9	What is the page limit or minimum page number for SOW?	There is no minimum nor a page limit.
10	How many applications are expected to support as part of BAA 2024?	I can really only give you traditional numbers. I think last year we received 278. The process is a little different this year so I am thinking somewhere in that 200 number

11	If you received a stage 1 recommendation to submit with feedback should you update the concept paper to incorporate the feedback and include that document with the Stage I package?	Yes, please feel free to update the concept paper and highlight areas that have been revised in the submitted version of the concept paper.
12	Do the Primary and Secondary Research Areas have to be related? For example, can we have the following: - Primary: I.A.1.a - Secondary: III.D.1.a	No, they don't have to be related
13	Are the proposal templates available in a Word format? Or are they only available as pdfs?	Yes, they will be made available in word format as well. Found as attachments in Sam.gov
14	Page 109 of the notice states that “the Full Proposal must list the names and proposed duties of the professional personnel, consultants, and key subcontractor employees assigned to the project.” Assuming Offerors need to include both key and non-key personnel, is it okay to list labor categories instead of names for non-key personnel? Given the uncertainty of the start date, this would provide Offerors the flexibility to evaluate and assign non-key staff closer to award, when available capacity is better understood.	I think that yeah, that make sense to me that we would accept that. I think that if you do have those names, it is always preferred to give us the names of the key personnel. If you are putting in a proposal in February and we are not contacting you until July, August, September 4 contract, those folks may have changed out or obviously, you're not going to hire someone if that is the case. So, I think showing that level of labor category with perhaps an example of the kinds of credentials those folks would have would be perfectly acceptable showing the key personnel.
15	how will the questions that offerors submitted in advance of this call (to the designated email address) be answered? will they be addressed during this call or afterwards in written form? sorry if this was already addressed in the first few min of the call and I missed it (joined late due to technical difficulties).	They will be addressed live and also the responses to all questions be posted on https://www.fda.gov/science-research/advancing-regulatory-science/fy24-fda-broad-agency-announcement-question-and-answer-session-01162024
16	If we complete the Concept paper first is it ok to submit it independently or should the package be submitted together?	All application submissions for February 20th should be accompanied with the checklist, concept paper, and full proposal, they can be submitted as separate "pdf" documents in the same email. But all of the applications, in order to be considered complete submissions would have to include concept paper as well as the full proposal that comprises of technical Volume one and cost proposal volume two.
17	For stage I, all three attachments (3-5) will be submitted via email as a single document or separate documents?	As separate document in the same email

18	For an academic lab, are we expected to submit a Good Laboratory Practice section?	Yes, for any proposals covered under the GLP scope.
19	If changes are made to the concept paper, is justification/reasoning required?	Justification or reasoning is not required, but please make sure you highlight the change for the version or sections of the text that has been revised from the original concept paper submission. No justification would be needed. Proposal title cannot be changed.
20	Won't the submission include a completed version of the the App 7 Cost Proposal Template in .xls in addition to the .pdf files?	That would be appreciated if you're going to fill out the Excel spreadsheet. If you could fill out the excel sheet in addition to the PDF, that would be appreciated. Again, just like the other answer, like with the SOW, if you have two different sections, as two different documents, does not count against your page limit.
21	For research institutions, does BAA contract cover indirect cost rate similar to a research grant?	It can. That is really up to how you propose. So yes, it could cover your indirect costs. But you need to break out what those indirect costs are. That comes down to your direct cost proposal. But a contract vehicle could be set up for that.
22	What is an RPF labor category?	Labor category should be tracked to GSA labor categories
23	I have a question about the FDA Goals that you are looking to meet. And a question about the term “research”. I want to submit educational research in teaching one health lessons and evaluating the pre and post test on knowledge on FDA’s mission and goals relative to middle school and high school cool level students. So, you have an educated consumer as they grow up and learn how to decertify for themselves how to evaluate social media information compared to FAD statements and data.	Yes, that can be considered under the definition of basic research under FAR. That is aligned with FDA's priorities and goals. I would like to request you to go through the presentation from Captain Skinner from FDA BAA day. Or look at the FY24 information for the listed health program.

24	Where can one see if the Early Concept Paper was recommended or rejected	You should have received an email on or before December 15th with a recommendation to submit or not submit stage I package. If you have not received this email, please contact FDABAA@fda.hhs.gov. We need an email with the title or charge area or attach the receipt notification that was sent to you when you had submitted the early concept paper and we will get back to you. Based on our understanding, all applicants have been informed a decision for recommendation except for one.
25	Is equal funding available in all three charge areas?	Unfortunately, the answer is "we don't know." Typically, not, but really it all comes down to the budget and we don't know what that is until it is allocated to us
26	Do you still need SAM registration for a small business as part of subcontract?	If you are a sub to another company, and the other company is the one that won the award, no, you do not need a SAM.gov registration.
27	Do you still need SAM registration for a small business as part of subcontract?	No, not as a sub-contractor.
28	How much early concept paper can be edited? Is it OK to edit concept paper title?	No, we would not recommend editing the concept paper title. You would be able to edit the concept paper overview where you are talking about or describing your goals, regulatory impact, or funding available, or funding proposed. Please note that if your project or proposal is considered for an award, at the time of contract, you are able to change the title of the proposal. But currently to ensure an error free review process, we do not encourage or recommend editing the concept paper title.
29	Is there any number of grant or contract applications by one applicant?	There is not.
30	I could not find the Safe Use Initiative announcement when searching on Sam.gov.	Okay, I am not sure. That does not appear to be a BAA question
31	For proposals that might seek to provide information on use of an FDA regulated product in use, can you explain how the Paperwork Reduction Act (PRA) would affect prospective data collection from clinicians/clinics or patients interacting with the product? For example, how would	So, I am not a matter expert on the PRA. I know about it from the contracting perspective and that you can count on, if the PRA applies to your proposal, you will have nine or more research — so how would surveys versus cohort studies be treated under the PRA? I

	surveys versus cohort studies involving administration of questionnaires be treated under PRA?	cannot answer that directly. If you would be collecting data for more than nine people, a very arbitrary number, but if you are collecting the data for more than nine people, the PRA would apply. The really important piece of that is in the past the FDA and our vendor teammates have definitely underestimated the sheer amount of time that the PRA adds to your efforts. So, if you feel or even think that the PRA will apply to your particular research area of interest, I would highly recommend that you look at the PRA and ad 9-12 months to your effort to account for that PRA process. And also, you may want to allocate your work in such a way that maybe there are other pieces of that research going on while you are waiting on that PRA so you don't go the whole time without seeing a payment. We have had some difficulties with the PRA in the past. While I cannot answer that directly, I do know that it applies quite often. And if you think it is going to apply, I would plan accordingly and add the 9-12 months to your plan accordingly.
32	the concept paper will be same as the one submitted for early evaluation, even if we have changed some of the aims? we will point out what has been changed in the technical proposal vs. concept paper as you specified.	Please highlight any changes in the newer version of the Concept Paper. As part of the concept paper, that is submitted as a requirement of the stage I submission package, please highlight the aims that have been revised compared to the optional early concept paper version that was submitted previously, so it is clear to the reviewers and program leaders that will indicate part of the concept paper sections that have been changed.
33	Could you please provide the formatting requirements in the chat so that I can ensure it is done correctly?	Please refer to FY24 BAA solicitation
34	Where can the HHS Small Business Subcontracting plan be found? Page 80 stated that there is a template provided to announcement, but I did not find any information on the website.	We do not have a template for this, and it is a business decision up to each large entity as to how they will subcontract.
35	Are there F&A provided like an NIH grant to the institution we work at?	Not at this time.

36	I believe I heard conflicting answers. It was confirmed that the terms biosketches and resumes are interchangeable. Then it was stated that biosketches are required for key personnel and resumes for everyone else. I don't believe there is a stated requirement in the instructions to provide biosketches/resumes for anyone but key personnel. Could you please spend a few minutes clarifying what format is required and which project team members it applies to? Thanks!	It is just key personnel. You can supply it for other key personnel, but it is only required for key personnel. And as far as format, we are kind of at the end of the format for that.
37	if a concept paper was recommended for submission but the proposal is not ready for the deadline, can it still be submitted after the deadline and be considered for the next cycle?	As Dr. Kinnera Chada mentioned, this is a rolling application. The short answer is yes, you can submit late, but know that your proposal would not be considered until such time as all the proposals have been reviewed and any decisions have been made on whether or not to fund those particular proposals. And basically, in that first quarter of FY25, your proposal might be reviewed and eligible for an award at that point. But it would be a significant delay in consideration. It would be for FY24 but using potential FY25 funds. And, for the late submission, please know that it is still required that you submit the full proposal along with the concept paper.
38	Can Ian reiterate the SAM.gov requirements pertaining to this FDA BAA? What needs to be done and when for US-based proposals?	The requirement is for us to award. You need to be registered in SAM.gov and eligible for all awards. Again, for the BAA, sometimes your small business status is wonky, or if you are a woman owned services business or disabled services business, it is wonky but would not hurt you for the BAA process. That said, I highly recommend, if at all possible, make sure you are 1) Registered at SAM.gov 2) Register the proposal. You are not barred from submitting if you are not there, but on occasion we go to award somebody, and they are not properly registered. I suspect most of you on the call can attest to this. If there is a problem with SAM it can take weeks, if not months to get it situated. I highly recommend you do that now if you haven't done so already.
39	Can the timeline and proposed budget be changed from the initial concept paper?	Yes, it can be changed. Please make sure to highlight the revisions made compared to optional early concept paper submitted version.

40	Can you speak to processes for intellectual property brought to a project, such as a software program and/or algorithms?	That is very much that it depends. Honestly, that could be its own one-hour TED Talk on intellectual property. Suffice it to say when I mentioned earlier about negotiation, that is one of the biggest areas that we negotiate is what is the intellectual and data rights look like? If you have something that is proprietary to you that already exists and you want to make sure that is protected going in, you are using your widget to conduct the research, absolutely that is protected. Now the outcome of that, the data that is the result of that, there can be significant negotiation there. Generally speaking, the government, if we are paying for data or paying for the results of data, we have what is called limited use rights of that and we can use that in any manner that we see fit short of giving it to another vendor. We cannot do that. That is another level of data rights. There are specific data rights for commercial entities and there are different data rights and honestly, they are a little bit more liberal for educational as additions. If you have intellectual property again that already exists going in with your proposal and you would be using that intellectual property, make sure it is labeled as such within your proposal so we can protect it accordingly. Outside of that, I would say that often that is a negotiation point, is where I will leave that.
41	Are there F&A provided like an NIH grant to the institution we work at?	Not at this time.
42	Thank you, Kinnera. What is the timeline for responses to questions being posted on the website noted above?	We will be posting the responses by 5 PM, EST of January 22, 2024.
43	how much total funds available for this year and how many projects will be awarded?	Unknown at this time.
44	Information on licensure and agreements with sub-contractors, collaborators and/or affiliations is required as part of the appendix. Which appendix should this information be included in? The biographical sketches appendix or another?	The bio sketches would be fine.
45	Cannot find the cost proposal template on sam.gov. Can you provide a link directly to this template? .	https://sam.gov/opp/d7baec2cffa242f0a9b52f5fc78e3be3/view

46	Aside from checking off items on the technical proposal checklist, is there anything else that we have to complete prior to submitting this with our full proposal package?	Stage I Submission Package should include checklist, concept paper, full proposal (volume I-technical proposal, Volume II- Cost proposal) and related appendix, statement of work
47	On pg. 106 for Resources Provided section, details on regulatory or compliance approvals is requested in the appendix. Please confirm which appendix this information should be submitted in.	This information should be included in the Volume I – Technical Proposal appendix for "Regulatory or Compliance Approvals" categories.
48	ON pg. 106 for Attachment 5, should the Draft Security Plan be included in Appendix 8. Security or in the Technical/Full Proposal?	In Appendix 8. Volume I – Technical Proposal appendix shall provide an overview of the "Security" related section. Details for Security and any waiver request need to be provided in Appendix 8.
49	On Page 92 of the BAA it says "use of color should be minimal and used only when necessary". Is this really for any color used in the template in or more related colorful images or using more than 2-3 colors?	My understanding is that as long as the images or color usage is 508 compliant, we are good.
50	Can you describe if there are any differences about what you are now calling “Scientific and Technical Information” section vs. the BAA from last year where there was an “introduction” section? Are these sections essentially the same? In addition, is the content of the SOW essentially the same between last year and this year, except the SOW has been moved now to the Appendix?	Introduction section is part of the scientific and technical information section for this year. In addition to introduction, you would see that objectives and also other information related to — give me a minute — let me go back to the slide where we talk about this. In addition to introduction and background, we also talk about stating the roles and objectives, as well as proposed outcomes and also the degree of innovation of the approach to offeror the capability after the implementation is also discussed. In addition to that as part of the scientific and technical section, what we are also introducing is research methods and approaches where we are requesting, depending on the proposal, for the applicant to provide clear and detailed descriptions of overall research methods, approach, or design, include any kind of scientific justification or rational research design. You will be able to find details as part of the template provided for technical volume I of the proposal under attachment five. Please Kinnera Chada's presentation for additional details.

51	Can a project be considered both applied research and development (with 2 phases) or should it be only ONE of the research categories	I would think, so not all the research categories are within each center and it becomes a funding issue. My recommendation would be that you keep it to one research category. Because once you start spreading things potentially across different program centers, you know you might have one center that is interested and another that is not or one that has funding and another that doesn't. So, my recommendation would be to keep it in the one research category.
52	I apologize if this question was asked before, but what is the maximum amount that can be given for the project	There is no max number, but funds are limited.
53	Is it OK to change the PI name mentioned in early optional concept paper?	Totally okay. You may want to point out that you have done so if you had a recommendation for an award.
54	Thank you for answering earlier. Do you still need SAM registration for a small business as a subcontractor to an academic institute?	Not as a subcontractor, no.
55	In the "Cost+Appendix+7+Proposal+Template" excel workbook, naming conventions are provided for the back-up document offerors need to provide in support of ODS and Materials/Supplies. Back-up documentation is also requested for subcontractors and consultants, but no naming conventions are specified. Does the FDA have a preferred naming convention for back-up documents related to subcontractors and consultants?	No, common sense naming is fine.
56	If revising the Early Concept Paper on a proposal submission that has already been recommended for a full proposal, does it still need to be kept within the 3-page limit?	Yes, that is correct. The three-page limit applies for all concept paper submissions. The 50-page limit applies for technical proposal volume I of the full proposal section. Item number 4 starts with the executive summary until the information related to risk mitigation plan. Items number 4-11 are included in the 50-page limit.
57	it is, FDABAA-19-00123. https://www.fda.gov/drugs/safe-use-initiative/safe-use-initiative-extramural-research Please get back to me Thanks!	https://sam.gov/opp/d7baec2cffa242f0a9b52f5fc78e3be3/view

58	On page 75 of the notice, in section “Preparation of Volume II – Cost Proposal” it states, “a cost summary (not to exceed 2 pages) shall be prepared and submitted in conjunction with the detailed cost propose.” Could the FDA please provide detail on its expectations for the content of the cost summary? Also, should the summary be submitted as a stand-alone document, or should it be a section within the cost proposal?	It can be a section within the cost proposal. But I would say is if the information required for the summary, if you look at the General tab on cost Appendix 7, the tab all the way to the left that says general, it says below is a summary of the proposed cost. That will fill in and be your summary. If you're using another format, if you are using those line items, I think that would cover you as part of your summary. I can actually go see here. Okay, yes, so use the line items under the General tab in Appendix 7 and you will be good to go. And if you use that Excel spreadsheet that we provide, that will auto fill in for you also.
59	On pg. 105 for Research Methods and Approach, it is requested that we include information on proposed population, proposed assessments and proposed regulatory, considerations, etc. Which appendix should this information be included in?	This information should be included as part of Scientific and Technical information (item 6 of the Volume I of the technical proposal). This information is included in the 50-page limit.
60	On page 15 of the notice, under the “Biographical sketches/Resumes/Roles and responsibilities” section there are instructions to provide “a list of the last three (3) government related contracts during the past three (3) years and all contracts currently being performed that are similar in nature to the BAA scope.” Since a fully compliant list might be quite long, especially with all of the details requested for each contract, could the FDA clarify if an offeror’s response to this requirement does or does not count against the 20-page limit for the Appendix? If it does count against the page-limit, would it be acceptable to provide 3-5 current contracts of similar nature versus a list of all current contracts of similar nature?	Contract being performed of similar size and scope. It can be (3) examples of past performance acceptable. It does count against the 20-page limit.
61	Is it OK to change the PI listed in early concept paper?	Yes, this is acceptable. Please make sure to highlight this revised information in your concept paper.
62	Is it OK to change the "budget of early concept paper"?	Yes, this is acceptable. Please make sure to highlight this revised information in your concept paper.

63	Does the applying organization need to have a registration in sam.gov at the time of submission? Or is it enough that it is registered if it is approved for grant receival?	So, remember — and again I know I belabored this point a little bit. We are not talking about grants. We're talking about contracts. You can't be registered in SAM solely for grants and not eligible for all awards. You specifically have to be registered for all awards. If you are registered just for grants, I cannot issue a contract to you and contracts are the only mechanism that I am legally allowed to issue from this BAA announcement. As to the first part of the question, do you need to have your registration up-to-date at the time of submission? No, you did not. Do I highly recommend it? Yes, I do. Again, it will prevent you from doing anything. But this way if you go in there and you see you are not up to date, again I was dealing with another company outside of the example I gave you earlier who had to get their SAM registration updated. And it took almost nine weeks to get it done. And so here we are a month out from the submission process. And in that scenario, it may take another month and a half on top of that. That could potentially derail an award for you. So highly recommend that you double check your SAM.gov registration anything that needs to happen to get that fixed, that you start on it now. SAM, I don't want to beat of our federal government teammates, but they have got quite a backlog. You may want to get on it now.
64	I appreciate if you could post all these Q/As to the website. Thank you!	Yes, we will post written responses by 5 pm of January 22, 2024
65	Will the FDA accept no smaller than 10pt font for graphics, tables, and charts? Thank you.	I believe that is correct. And I do see a question about the formatting requirements. Those are all in — we have gone over a number of them in this particular thing. It is a little bit much to put in the chat, but it is all in the BAA document. And I did answer a couple of these off-line answering where the SAM.gov posting is. If you look there, I put links directly to the SAM.gov posting. Again, somebody is put in there that they didn't find the posting. It is all in there in SAM.gov. If you go to the SAM.gov posting and scroll down to the attachments and links, it is in there.

66	On page 15 of the notice, under the “Biographical sketches/Resumes/Roles and responsibilities” section there are instructions to provide “a list of the last three (3) government related contracts during the past three (3) years and all contracts currently being performed that are similar in nature to the BAA scope.” Can you clarify if only contracts are allowed, or if the offeror can cite cooperative agreements as well?	So, where it said "cite cooperative agreements" absolutely that would be acceptable site performance. And then also in addition to these other updates, once we have all the questions and answers and recordings and everything, I will post links to that on SAM.gov and then you will post that to the FDA website.
67	1. What are the key challenges for PLGA-based generic drugs to be approved? 2. For the 3 PLGA-based generic drugs that were recently approved by FDA, how were those challenges addressed? 3. Are there specific CQAs that have been prioritized by the FDA?	1. PLGA-based drugs are a group of products with unique complexities as each product/dosage form may have its own challenges. In general, the challenges can be discussed from three aspects including regulation, quality (formulation development and manufacturing), and bioequivalence. Per regulation, most of PLGA-based generic drugs are required to demonstrate qualitative (Q1) and quantitative (Q2) sameness to the reference products. FDA has done extensive research to better understand characteristic of PLGA polymers and develop analytical methods for polymer characterization. To support quality assessment, PLGA drugs require comprehensive formulation characterization to support formulation development and manufacturing. Lastly, all PLGA based drugs are long acting. Clinical bioequivalence studies are lengthy and often require patient populations due to safety concerns. 2. FDA has established guidance on how to assess formulation Q1Q2 sameness for supporting generic development. Generic applicants can obtain feedback from the FDA regarding Q1Q2 sameness of their proposed test formulations via controlled correspondence. To support bioequivalence studies, FDA publishes product specific guidance describing the current thinking on how to establish bioequivalence of the proposed test product. FDA also meets with generic applicants to address appropriate technical and/or regulatory questions via pre-ANDA development meetings to facilitate generic development. 3. PLGA-based drugs involve different dosage forms including solid implant, microspheres, and in situ forming depots. Each of these dosage forms has their own CQAs. FDA has funded research projects for these dosage forms with various focuses. A few example focuses are: 1) advanced imaging technology and AI based

		image analysis to better understand microstructure and their impact on drug release; 2) impact of hot-melt extrusion process and polymeric characteristics of PLGA polymers on surface morphology, porosity, drug content uniformity, drug release of solid implants; and 3) impact of raw material and manufacturing process on characteristics of microspheres including particle size/size distribution, porosity, surface morphology, drug loading, and drug release. FDA aims at obtaining improved understanding on the impact of identified quality attributes to guide the generic development and assessment.
68	Are Multiple PI's permissible, with a corresponding PI (following NIH's MPI model)?	Yes, but there should be a single primary point of contact
69	Attachment 3. BAA Checklist Pg. 1, pg. 99 Is the BAA Application Checklist required with submission of the Full Proposal? If so, should this be submitted as a separate, standalone document or included with the Full Proposal and where (first page? Appendix?)	Yes, Application checklist is required for the Stage One Application Package. It can either be submitted as a standalone pdf document or attached as first page of the Full proposal.
70	Resources Provided, a Pg. 106 Is there any guidance on who should be included as key personnel?	This is a business decision
71	Preparation of Volume I – Technical Proposal Pg. 72 Can text in tables, figures or charts be smaller than 12-point font Arial?	No smaller than 10-point font

72	Attachment 5: Technical Proposal Template Pg. 103 Please confirm that information concerning Security Planning, Intellectual Property and the Bibliography are outside of the 50-page limit	Yes, only sections 4-11 are included in the 50-page limit for Volume I of Technical Proposal. See slide 21 of Kinnera Chada's presentation.
73	Resources Provided, b Pg. 106 Information on licensure and agreements with sub-contractors, collaborators and/or affiliations is required as part of the appendix. Which appendix should this information be included in? The biographical sketches appendix or another?	Please include this information "Contractual Agreements" section of Appendix for Volume I of Technical Proposal. See slide 21 of Kinnera Chada's presentation.
74	how close does the final budget need to be to the total provided in the concept paper?	This is a business decision

75	Part III Proposal Preparation and Submission p. 68 If the early concept paper submission was recommended for the full proposal, please confirm that Offerors should submit an updated concept paper based on the submitted proposal or if Offerors should submit the original concept paper with the proposal submission.	As discussed in Dr. Kinnera Chada's presentation, offerors, are free to submit a revised proposal. But please make sure to highlight the areas that have been revised as part of your concept paper submission which would be included as part of the package.
76	Part III Proposal Preparation and Submission p. 71 Please confirm that we can use a font size for tables and exhibits that is no less than 10-point font.	Yes, that is correct
77	Attachment 5: FY24 BAA Volume I Technical Proposal Template p. 103 The table on page 103 lists the required Security Planning section as both part of the technical proposal components and as an appendix. Please confirm that the Security Planning section should be included as an appendix and counts towards the 20 pages of the Volume I appendix section	Volume I – Technical Proposal appendix shall provide an overview of the "Security" related section. Details for Security and any waiver request need to be provided in Appendix 8. It is an appendix and does not count toward the page count. Please review Dr. Kinnera Chada's presentation. Volume I – Technical Proposal appendix page limit has been updated to 30 pages.
78	Attachment 5: FY24 BAA Volume I Technical Proposal Template p. 103 Please clarify the page limits for the required elements in the table on page 103. Are we correct to assume that the 50-page limit applies to items 1-11 (as noted on page 103 section A header) and items 12-14 should be answered concisely by there is no exact page limit for these items?	Yes, that is correct

79	Volume I-Technical Proposal Appendices p. 107 Please confirm that Bio sketches and resumes are being used interchangeably.	Yes, that is correct
80	Volume I-Technical Proposal Appendices p. 107 Please confirm that the requirement is to submit Bio sketches for key personnel and resumes for all other named personnel.	Yes, that is correct

81	First, my understanding of the BAA instructions is that the concept paper, volume one and volume two should each be separate PDF files but should be sent together. Please let me know if this is correct or incorrect. Second, for volumes one and two, we did not see instructions on whether the pages have to use portrait orientation or can use landscape orientation. Could you let us know if we can use landscape orientation for select pages?	Yes, that is correct, and you may use landscape where appropriate
82	Preparation of Volume II - Cost Proposal p. 75 Is FDA expecting offerors to choose either a severable or non-severable cost proposal response per Topical Area, or are offerors able or expected to propose a hybrid approach based on the proposed deliverables? If a hybrid approach is allowable or anticipated, would FDA prefer the offeror present the cost proposals separately and provide a summary table that incorporates both severable by year and non-severable under the Base Period Costs?	Yes, you definitely can propose a hybrid approach. I would say that if you do so, a summary table showing both severable and non-severable would definitely be helpful and to your advantage for sure. And then yes to the first part of the question, are we expecting to choose severable or non-severable, yes, we are. But again, if hybrid makes the most sense, you can propose that.
83	We have published a proof-of-concept for in situ stability test of mRNA vaccines. Would FDA support this project?	It sounds like an acceptable topic for proposal. We cannot say that yes, we would support it or know we wouldn't, but it certainly can be considered if that was proposed.
84	Can organizations (company/university) outside the U.S. apply?	They can. And we looked and we have a number of BAAs and regular normal contracts we have with organizations outside the US. But like I said, you do have to be registered under SAM.gov and there are additional steps for foreign entities to do that. Go to the State Department website.
85	Are there timelines, averages, etc. available to understand timelines for pre-award activities? solicitation thru award, etc.	I don't really want to give timelines necessarily other than as Dr. Kinnera Chada mentioned, this is a rolling application process. Obviously, the proposals are all due February 20th. And all proposals

		that we funded with FY24 money would all be awarded prior to the end of the fiscal year. We hope for prior to August and so we are not rushing around at the end of the fiscal year like we do. But outside of that I really don't want to give hard timelines because it is really dependent on funding, the technical teams, and my ability to get the contracts signed. I will say as a note for everyone for solicitation, the BAA process itself is the solicitation process. By the time you get to the technical review, think of that as the pre-award, but the post solicitation process if that helps. The percentages of the future current awards, I am not sure if that is published yet. If you were to Google our goals for last year, those are available. But I don't know if we have gotten the FY24 small business goals just yet. And again, as I covered earlier as far as required set-asides, there are no required set-asides for the BAA program.
86	What is FDA's policy regarding sub-contractor management, and small biz required set asides? What % of future/current awards?	As far as a subcontractor management and small business required set-asides, all the same rules apply for that. If you are small business, we do have the subcontracting plan but there is no small business requirement there. If you are a large business, you will be required to put in a subcontracting and small business plan.
87	Provide Other Transaction Authority (OTA) opportunities/requirements at FDA. Specific OTA instruments or related programs?	The FDA in general does not use a lot of OTAs. Specifically, through the BAA program, we only award contracts. We do not award — we don't award ETAs, BOAs, some of the other things that OTA uses. The FDA doesn't use that in general, but specifically for the purposes of today we don't leverage OTAs for the BAA process. The result is for all of the proposals, it is a contract
88	Where can we find opportunities for small biz?	No set-asides for the BAA process. However, you can check with your small business specialist within the FDA or HHS. You can check with your local small business specialist that you deal with, and they can help you locate those. You can search set-asides on SAM.gov and FDA. And just on my team, we have dozens per year, and there are many teams that deal with contracting. So, we had a fairly significant small business goals for last year and we met all but one of them as an organization. There are a lot of opportunities for small businesses.

		What I would say is learn how to navigate SAM.gov and you will find those opportunities out there.
89	If awarded funding, which portal will be used for monthly reporting requirements? Can you please describe the reporting upload process?	As far as reporting, that really is contract dependent. Mostly it is more — less of a portal type situation, more like giving your monthly reports to the Contracting Officer's Representatives and the contracting Officer and generally that is kind of an informal email type process generally speaking. If we are talking about — I will say this — because I cannot remember if I saw it as part of this question initially order the part of the question. The one thing that I definitely wanted to make sure that people understand as far as a portal would be for invoicing. And that is the IPP platform. All contracts awarded through the BAA is using the IPP platform. Be aware of that.
90	Clarify HHSAR clause 352.231-70 Salary Rate Limitation for $212,000 cap.	This is the HHS version of an Executive Order. This comes from the Office of the President. It has been around for quite a few years. Essentially, every few years there is a cap on what we can pay, we, meaning the government, can pay the executive service and this year it is $212,000 for our most senior folks. That is their cap. That Executive Order ensures that we are not paying anyone more than our executive service folks. Now I know digging into this question there was a "what if we have somebody at our organization that gets paid $300,000 a year?" Well, unless they are working 100% on this contract, there is just a percentage of that. It is a percentage of their time as applied to the contracts. If they are not giving 100% of their time than we are not paying 100% of their salary. It is the percentage of the salary as it pertains to the work that they are doing on that contract.
91	What constitutes “research” for this solicitation? Does education based on informing the public on one health considered appropriate?	The time limit is five years maximum. In general, five years is the limit depending on the action. As far as the amount that is case-by-case basis. You can look back at previous years of awards.
92	Is there an amount or time limit on the proposed budget?	No, I don't know the budget
93	If there are subcontracts, does the subcontract's indirect cost become part of the main site's direct cost?	No that stays indirect cost. You can list them out separately, but they can remain indirect cost.

94	I was wondering if Appendix 7 Cost Template was required or if we could use a different template as long as it is detailed.	We provided Appendix 7 because we realized that doing cost proposals was new and exciting territory for a lot of people. So, we were giving folks a template to use, but it is not required. Again, if you have an accounting system or have some other template or spreadsheet or however, it is that you as a business provides a type of information that the template does, then by all means use what you have.
95	would it make sense to propose an overarching IDIQ-type program that encompasses the varied solutions for all our members OR should we stick to the letter of the BAA and submit 1 proposal per solution? MxD is prepared to manage multiple projects under such a structure (we do it for DOD quite often), but we weren't sure if proposing a single, overarching programmatic solution would knock the proposed projects' capabilities from consideration.	The short answer is yes, it would. The BAA process very specifically is not designed to meet an Agency need. It is for the vendors and the educational institutions to propose solutions for either projects of public good or research. Basically, to think of things that the government hasn't thought about. IDIQs are really — we know what our need is — but we don't know how much of that service or good we will need to do that. So, without digging into the FAR, essentially, we are barred from issuing any IDIQ off of the BAA process. So, I absolutely would not recommend putting in a proposal for an IDIQ because I don't have a way to award it.
96	Regarding security planning, we would like to request for a waiver. I am not sure what the process is to submit this request?	Request in the security planning appendix. Should a contract be awarded the security waiver process is an FDA function. It should be noted that it is recommended that any planning timelines factor that a waiver will not be granted.
97	Would cancer research-related BAAs be considered Paper Reduction Act (PRA) exempt due to the 21st Century Cures Act?	Exemption of PRA approval is dependent on proposal's objectives and methods. PRA for each proposal will be handled on a case-by-case basis. Recommend inclusion of 9-12 months in the proposal timeline to account for PRA approval
98	Whether it is accurate that although Labor Categories are submitted these are understood to be on the basis of cost rates - not T&M rates - and therefore exclusive of fringe benefit costs, indirect costs, and/or fee	Please indicate whether your labor categories are fully burdened
99	Whether it is therefore understood that unlike under T&M type awards, actual costs billed can vary depending on adjusted hourly rates charged on the basis of individual assigned staff and actual hours worked inclusive of uncompensated overtime.	That is a correct assumption

100	Whether the proposed rates, unlike under T&M type awards, are therefore not understood as ceiling rates since actual cost rates can be higher on the basis of individual assigned staff and actual hours scheduled during a given period.	That is a correct assumption. There will be an overall not to exceed ceiling to any cost contract
101	Is the rate of the Federal Executive Schedule Level II, effective January 2023, still applicable?	Yes.
102	Can you confirm on the starting date?	That is award date dependent
103	It was not clear to me from the documentation provided in and with the BAA what to use a potential start date for the contract for the purposes of developing the proposed budget. Would 9/1/2024 be appropriate (as near the end of FY24)? Or can you provide other guidance?	As early as April 1st, 2024, and late as September 30th, 2024
104	Cost Appendix 7 Proposal Template. For commercial contractors/vendors intending to propose service on a Firm-Fixed-Price (FFP) basis, is there is an alternative spreadsheet omitting the request of a detailed cost breakdown (e.g., relative to cost type contracts such as indirect rates, fringe, overhead, etc.) that we can utilize for submitting FFP pricing? If not, are we able to provide an alternative FFP price proposal for consideration?	*Are we able to provide an alternative FFP price proposal for consideration* - Yes
105	FY24 BAA Notice v4.0 – Preparation of Volume II Cost Proposal**.** Will FDA, please clarify that FFP commercial contractors/vendors exempt from Cost Accounting Standards (CAS) are not required to submit Certified Cost and Pricing Data (FAR 15.403-4(a)(1)) even if our price is over $2M?	That is correct

106	FY24 BAA Notice v4.0 - Introduction Section 5; Preparation of Volume II Cost Proposal**.** The BAA requests a detailed cost breakdown that commercial contractors exempt from CAS are not able to provide; The contractor does not hold a cost accounting system which aids the breakout of cost categories such as such as the direct labor, fringe benefits, materials and supplies, other direct costs, and indirect costs. The contractor therefore exclusively offers Firm-Fixed-Price (FFP) commercial services where their market prices are established in the course of ordinary trade between them and their clients which are free to bargain, and can be substantiated through competition or from sources independent of the vendor (Reference: 48 CFR §2.101). In lieu of providing a breakout of the references costs and being evaluated under Part 31 – Contract Cost Principles and Procedures, will the FDA please allow the vendor to submit historical pricing documentation to enable FDA's price reasonableness evaluation (this documentation can demonstrate performance with similar public sector clients, and payment of the commercial rates proposed herein to assert the commerciality of price)?	Yes, that is fine. Any other than certify cost and pricing data is acceptable
107	I wanted to ask a few additional questions. If the applying organization (SOLDA – Society on Liver Disease in Africa) is relatively new (since 2022), is that imposing any constraints on it applying. I didn't see any such restrictions in the file, but just wanted to make sure we are on the safe side here. I have downloaded all the required documents published on the SAM and FDA website, and wanted to confirm if only those 3 documents need to be filled in?	Being a new organization does not restrict you from applying. Recommend reviewing the submission requirement in the BAA announcement.