Biomedical Research APS
Questions & Answers

1. In objective 2 of the APS (on page 1), line (b) contains an "and" implying that the MPTs should have all of the listed properties (a, b, and c). Later in Aim 4 on page 6, the same list is repeated without the "and" implying that the MPT should be contraceptive plus have one of the three properties. Should proposals addressing Objective 2/Aim 4 satisfy all 4 criteria, or be contraceptive plus one of the other three criteria?

Answer: Proposals addressing Objective 2/Aim 4 should be contraceptive plus ONE of the other three criteria.

2. On page 3, under Aim 4, "**Foster mid- to late-stage FP/RH product development**", could you please clarify whether all three of the second group of components must be met (i.e., whether there is an implied "and" after each item), or whether that really means "and at least one of the following:", or something else:
   a) protect against HIV, other STIs, and/or RTIs
   b) are effective when used only occasionally or intermittently
   c) confer additional health benefits

Answer: See answer to Question #1.

3. Can an organization submit more than one concept paper? If each organization should submit only one concept paper, can it contain multiple projects? If so, is each project allowed 5 pages or is the entire concept paper limited to 5 pages?

Answer: There is no limit on the number of concept papers that can be submitted by an organization, and each concept paper can contain multiple projects. However, each concept paper, no matter how many projects it includes, cannot exceed 5 pages.

4. Can more than one project be submitted for a given Aim of the APS?

Answer: Yes, but see answer to Question #3 regarding page limitation.

5. Will you need experienced peer reviewers for this program?

Answer: Expert reviewers for this program have already been chosen.

6. Can cost sharing be proposed to allow for a larger project to be conducted? If so, is there any restriction on how we propose the cost share?

Answer: Yes, cost sharing can be proposed to enable a larger project. Please refer to 22 CFR 226.23 on guidance for what is allowed and not allowed regarding cost share. http://edocket.access.gpo.gov/cfr_2007/aprqtr/pdf/22cfr226.23.pdf

7. The APS addresses several AIMS. Would it be possible for one entity - one company - to submit more than one concept paper if it believes that it has products or methods that fall into two AIM categories?

Answer: Yes; see also the answer to Question #3.

a) Would it be possible for a single entity to submit more than one concept paper if it has two distinct products that fall into a single AIM category?

Answer: Yes; see also the answer to Question #3.

8. Should each concept paper address a single product or methods. Or, alternatively, if there are two or more related products or methods can they be studied, together, under one award - with appropriate rationale for their being linked in this way?

Answer: Concept papers may address single products or multiple related products, under one or more Aims. If a concept paper addresses more than one Aim, the maximum award would consist of those amounts indicated under the respective Aims. For example, if a concept paper chose to address Aims 1 & 4, the combined allowable award would be $10 million ($5 million from Aim 1 and $5 million from Aim 2). Any concept paper addressing more than one Aim is still limited to 5 pages.

9. If participants are selected in a manner governed under the Belmont report and OPRR, can those same participants, post a reasonable separation period, be asked and paid an honorarium as part of the research on a different product - if covered by the award? Given the difficulty in selection and maintenance of participants and acknowledging potential bias of attitudes, if the results are empirical and attitudinal, then a single population - with appropriate instruction and their acceptance, might be a most effective use of resources - particularly if the research calls for Early and Later Phases where there would, at least, be two populations.

Answer: This question is beyond the scope of work for a concept paper, and would be addressed should a full application be requested.

10. Should clinical trial Participants be restricted to the US - or are Participants allowed, under the same supervised criteria, if selected from African populations. This is particularly important if a secondary or later phase is envisioned based on successful milestones or performance standards met in an earlier Phase.

Answer: There is no restriction on the geographic location of clinical trial participants.

11. Are there restrictions as to award criteria concerning the necessity of US Citizenship for the Principal Investigator - and/or other study participants?

Answer: There are no restrictions on citizenship of the PI and/or study participants.

12. If a company has its own IRB - can that board be used to supervise the research?

Answer: Yes; however, involvement of other IRBs may be necessary.

13. Will it be possible to add key personnel and/or key research sites after the submission of the Concept Paper but before the beginning of any awarded research?

Answer: Yes.

14. Would a proposal covering a monthly contraceptive microbicide vaginal ring be appropriate under this RFP?

Answer: Yes, given a clear rationale for how such a product would address one of the four Aims.

15. Does USAID have a cap on IDC for this cooperative agreement? If yes, what is it?

Answer: USAID interprets this question as referring to caps on Indirect Costs (IDC). If this is the case then the cap on the indirect cost rate would be based on the rates that are on the organizations NICRA or approved Indirect Cost Agreement with another agency. If the applicant does not have an approved Indirect Cost Agreement, then the applicant shall propose a rate. If the applicant is requested to submit a full application, then the applicant will also be asked to submit financial information to back up the rate proposed.

16. Does the $ amount indicated (i.e. $5 million) includes the IDC or is it only total direct cost of the project?

Answer: The amount indicated includes the IDC.

17. Does the $ amount indicated (i.e. $5 million) includes the 10% cost share or is the cost share over the total amount awarded (i.e. if we are awared 2 million, we would in addition provide 200,000 above the awarded amount in cost share)

Answer: The amount indicated does not include the cost share.

18. Does USAID allows to have 2 co-PIs or only one PI?

Answer: There is no limit on co-PIs.

19. Does USAID suggest that bidders identify subcontractors and/or collaborating partners in their concept papers or would that be determined in the full proposal?

Answer: Subcontractors and/or collaborating partners can be identified in the concept papers.

20. We are assuming that in Aim 4 "support further testing of promising compounds and delivery methods that exhibit high contraceptive effectiveness, and a) protect against HIV, other STIs, and/or RTIs, b) are effective when used only occasionally or intermittently, c) confer additional health benefits" that a, b, and/or c have to be met. Please clarify that the product must meet one or two but not all of these criteria.

Answer: Please see the answer to Question #1.

21. Please confirm that these research initiatives can have one principal investigator and additional co-Investigators.

Answer: Yes; see also answer to Question #18.

22. Please confirm that the reference materials and annexes cannot exceed a total of four (4) pages.

Answer: Yes – please do not exceed the four (4) page limit to reference materials and/or annexes submitted with the concept paper.

23. While the APS states that the intent is to foster mid-stage and late stage product development where the payoff of regulatory approval and introduction would be likely within five years, many (most?) promising approaches that incorporate an anti-

STI or anti-HIV active compound with a highly effective contraceptive are at an earlier stage of product development. Would you consider proposals for work at an earlier stage for this important category of products?

Answer: ***Please note that on page 2 of the APS, it states: "…the APS is not soliciting for discovery, screening, preclinical, or early clinical R&D of new leads…", so any proposal would have to meet the criteria of mid- to late-stage development.***

24. The cover letter states that "USAID anticipates obligating up to a total maximum of $5 million **for all** cooperative agreements awarded" under Aim 1. However, page 3 of the APS states that "**For each** award [under Aim 1] USAID anticipates obligating up to a total maximum of $5 million." This discrepancy between the cover letter and APS also exists for Aims 2, 3, and 4. We assume that the cover letter statement is correct, and that USAID anticipates obligating up to a total maximum dollar value **for all** cooperative agreements awarded under each Aim. Please confirm that this assumption is correct.

Answer: ***The statement on page 3 of the APS is correct – the maximum noted under each aim is for <u>each award</u>, depending upon availability of funds. For Aim 1, USAID anticipates obligating up to a total maximum of $5 million for each award (i.e. Aim 1: 2 awards @ $5 million each = $10 million for Aim 1). For Aim 2, USAID anticipates obligating up to a total maximum of $2 million for each award (i.e. Aim 2:3 awards @ $2 million each = $6 million for Aim 2). For Aim 3, USAID anticipates obligating up to a total maximum of $1 million for each award (i.e. Aim 3: 2 awards @ $1 million each = $2 million for Aim 2). For Aim 4, USAID anticipates obligating up to a total maximum of $5 million for each award (i.e. Aim 4: 2 awards @ $5 million each = $10 million for Aim 4). The total ceiling possible for all awards under this APS is $28 million.***

25. On page 6, the APS states that "the summary budget should clearly identify the major costs by line items." We assume that applicants who are successful in the concept paper stage will be given an opportunity to revise these "line item" estimates in the full application. Please confirm that this assumption is correct.

Answer: ***Only upon USAID request will the offeror be allowed to revise the major costs by line items.***

26. On page 6, the APS requests that applicants "provide information on your cost share as part of the budget." Please confirm whether providing the total estimated amount of cost share is considered sufficient "information". If additional information is being requested, please state what specific "information" is needed and if this information may be considered outside of the one page limit.

Answer: ***Yes – providing the total estimated amount of cost share is sufficient information for the concept paper. Additional information may be requested in the full application.***

27. On the cover letter, the APS states that "Applicants are recommended to provide a 10% cost share." On page 6, however, the APS states that "Cost sharing of at least 10% is expected." Please clarify which statement is correct.

Answer: ***Applicants are recommended to provide <u>at least</u> a 10% cost share.***

28. The APS ends at "Page 6 of 7." Please provide "Page 7 of 7" or provide clarification on the total number of pages in this APS.

Answer: ***The APS itself consists of 6 pages. The entire posting consists of 9 pages (cover letter – 2 pages; acronym sheet – 1 page; APS – 6 pages)***

29. On the cover page of the APS call, under Aim 1 – it states: "USAID anticipates awarding up to two (2) cooperative agreements ….USAID anticipates obligating up to a total of $5 million for all cooperative agreements awarded under this Aim." Whereas on page 3 of 7 – Section II – Award Information – Funded – Aim 1 is states: "For each award, USAID anticipates obligating up to a total maximum of $5 million." Could you please clarify if it is USAID's intent to obligate a maximum of $5 million per CA or $5 million for both CAs?

Answer: ***Please see answer to question # 25.***