## Attachment 4: FY25 BAA Application Concept Paper Template

Concept Paper content shall adhere to the 3-page limit (includes **Concept Paper Cover Table** and **Concept Paper Overview)**, Page Size: 8 ½ x 11 inches; Spacing – single; Margins – 1 inch; Font – Arial; Font Size – 12. Tables, charts, references, and figures can use Font – Arial; Font Size – 10. Usage of color needs to be 508 compliant. **If the submission exceeds the number of pages specified, only the pages up to the limit will be reviewed.** Incomplete Concept Paper submissions will **not be evaluated and shall be disqualified from consideration**. If FDA recommends a Stage One Package Submission for an Optional Early Concept Paper, the applicant may submit a revised concept paper for a Stage One Package Submission. However, the revised Concept Paper should highlight any fields that were revised from the version of the Optional Early Concept Paper. For additional details, visit

**Concept Paper Cover Table:**

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| --- | --- |
| **Project Title**: | |
| **Charge Area**: | **Regulatory Science Topic Area of Interest**: |
| **FDA Regulated Areas**: | **Demographics and Populations**: |
| **Primary Research Area**: | **Secondary Research Area**: |
| **Offeror**: | **Offeror Contact Information**:  **Name**-  **Email**-  **Phone**- |
| **Principal Investigator**: | **Affiliations**: |
| **Research and Development Justification:** Broad Agency Announcements, as described in the Federal Acquisition Regulations (FAR), may only be issued for the procurement of Research and Development (R&D). All acquisitions resulting from this announcement must meet one or more of the FAR definitions for basic research (See FAR 2.101(b)(2)), applied research (See FAR 35.001) and development (See FAR 35.001). Include a brief and clear justification describing how the project falls under the FAR requirements for R&D work. | |
| **#Does the proposal involve DURC, PEPP, and/or nucleic acid synthesis (See Part III, Section 9.1 for details)?  Yes** or **No** | |
| **Between 10/4/2024 to 11/8/2024, has the Offeror submitted an Optional Early Concept Paper for FY25 BAA?** Yes/No. **If Yes**, state  **Primary Research Area** (i.e, II.B.7.e) and **Status** of previous submission (i.e., Recommended for Stage One Package Submission (BAA Number provided- Highlight revised sections), Not Recommended for Stage One Package Submission, Unknown). | |

1. **Concept Paper Overview (Highlight any revised sections from Optional Early Concept Paper)**
2. **Research Strategy**:
3. **Aims:** Succinctly list the **specific objectives of the proposed research** (State the problem/objective and provide motivation for addressing that problem/objective) and **primary scientific challenges being addressed**
4. **Methods:** Clearly **describe the approach**, **description of level of effort, and the nature as well as extent of the anticipated results of the effort** (one Figure that is a 508 compliant picture or graphic that illustrates the research or concept can be included)
5. **Considerations: Brief description of the Offerors intellectual property ownership, data ownership, or licensure**; **statements on work experience for similar effort with FDA or another agency**
6. **Regulatory Science Impact** 
   1. How does this research address an unmet need or fill a critical knowledge gap to advance regulatory science and the program’s priorities? How might FDA apply the research findings to the development of new tools, approaches, or standards? Please explain the benefits of proposed technology and challenges and how the proposed project aligns with the objectives of FDA Regulatory Science
7. **Proposed Deliverables and Funding**
   1. List of the major goals, deliverables, or milestones and proposed funding by project year. Total proposed funding is the Base period cost plus each option period with no more than 5 years total.

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| Milestones | Timeline | Funding |
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| Total Proposed Funding: | |  |