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| --- | --- |
| **Funding Opportunity Title:** |  |
| **Mechanism:** |  |
| **PA #:** |  |
| **URL:** |  |
| **Submission Status:** |  |
| **Submission Date:** |  |
| **Organization/Institution:**  |  |
| **Study Section:** |  |
| **Principal Investigator:**  |  |
| **Proposal Title:** |  |
| **Co-Investigators:** |  |
| **Consultants:** |  |

**Summary Abstract (30 lines)**

**Public Health Statement (3-4 Sentences)**

**Response to Reviewers**

(1 page)

If Revising Application

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| --- |
| **Response to Summary of Discussion:** We thank the reviewers for their thoughtful comments. These comments strengthened the overall scientific premise and rigor of the proposed study. |
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**Specific Aims Page**

(1 page)

**Research Strategy**

(6 to 12 pages, includes Significance [Scientific Premise], Innovation, Preliminary Studies, Approach [Rigor and Transparency])

**A. Significance**

**B. Innovation**

**C. Preliminary Studies**

**D. Approach**

**Section 4.1 - Brief Summary**

(Copy-n-Pasted into E-Forms)

Directions: Enter a brief description of objectives of the protocol, including the primary and secondary endpoints. The Brief Summary is limited to 5,000 characters and spaces

**The Brief Summary is no longer included, just the Study Description.**

**Section 4.2.a - Narrative Study Description**

(Copy-n-Pasted into E-Forms)

Description: Enter a narrative description of the protocol. Studies differ considerably in the methods used to assign participants and deliver interventions. Applicants will need to show that their methods are appropriate given their plans for assignment of participants, delivery of interventions, and data collection and analysis.

Describe how participants are assigned in groups or clusters (e.g., families, providers, clinics, schools, communities), and/or when interventions are delivered to groups or clusters, and/or how and when observations on individual participants are analyzed, and any special methods that are required for analysis and sample size.

The narrative description is limited to 32,000 characters and spaces

**Section 4.2.c – Interventions**

(Copy-n-Pasted into E-Forms)

Name: Enter the name of the intervention. The name must be unique within each study record. The name is limited to 200 characters.

Description: Enter a description of the intervention. The description is limited to 1,000 characters.

**Section 4.3 – Outcome Measures**

(Copy-n-Pasted into E-Forms)

|  |  |  |  |
| --- | --- | --- | --- |
| **Type** | **Name**(255 Characters including spaces) | **Time Frame**(255 Characters including spaces) | **Brief Description**(999 Characters including spaces) |
| Indicate: Primary, Secondary or Other |  | Indicate when a measure will be collected for analysis (e.g., baseline, post-treatment). | Describe the metric used to characterize the outcome measure if the metric is not already included in the outcome measure name. |
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**Section 4.4 – Statistical Design and Power**

**Statistical Power, Analyses and Missing Data**

**References**