

1_Funding_Oppportunity_Overview

Opportunity ID: PAR-25-283 **Name:** Innovative Mental Health Services Research Not Involving Clinical Trials (R01 Clinical Trials Not Allowed)
Award Amount: Not specified in the context **Award Project Period:** Not specified in the context **Link to Opportunity Announcement:**
<https://grants.nih.gov/grants/guide/pa-files/PAR-25-283.html>

Project Complexity: 1) **Regulatory:** Low - The project does not mention high regulatory requirements, and it is not focused on areas with heightened regulatory scrutiny such as human subjects research involving sensitive populations. 2) **Data Collection and Management:** Medium - The complexity could increase if there are multiple sites involved but is unspecified in the context provided. 3) **Statistical Analysis and Manuscript Development:** Low - The lack of complexity in analysis is inferred as it does not mention non-standard statistical processes or advanced methodologies. 4) **Information Technology:** Low - Assuming standard software and IT services are used without unique customization. 5) **Operational:** Low - Standard project administration is expected, given the lack of mentioned complications in site onboarding or coordination. 6) **Financial:** Low - Budget management appears straightforward without complexities indicated.

Required Budget Form: Since this opportunity is not a research grant (it is explicitly not involving clinical trials), the detailed form (R&R Budget Form) is required.

2_Personnel_Effort

Final Personnel Effort and Person Month Allocation Table:

Role	Year 1	Year 2	Year 3	Year 4	Year 5
DCC Principal Investigator	15% (1.8 PM)	15% (1.8 PM)	15% (1.8 PM)	15% (1.8 PM)	15% (1.8 PM)
Clinical Data Manager	60% (7.2 PM)	60% (7.2 PM)	60% (7.2 PM)	60% (7.2 PM)	60% (7.2 PM)
Statistician	50% (6.0 PM)	50% (6.0 PM)	50% (6.0 PM)	50% (6.0 PM)	50% (6.0 PM)
Clinical Project Manager	75% (9.0 PM)	75% (9.0 PM)	75% (9.0 PM)	75% (9.0 PM)	75% (9.0 PM)
Business Project Manager	25% (3.0 PM)	15% (1.8 PM)	10% (1.2 PM)	0% (0.0 PM)	0% (0.0 PM)
Ops Leader	10% (1.2 PM)	10% (1.2 PM)	10% (1.2 PM)	10% (1.2 PM)	10% (1.2 PM)
Administrative Coordinator	10% (1.2 PM)	10% (1.2 PM)	10% (1.2 PM)	10% (1.2 PM)	10% (1.2 PM)
Finance	5% (0.6 PM)	5% (0.6 PM)	5% (0.6 PM)	5% (0.6 PM)	5% (0.6 PM)
Biometrics Management	5% (0.6 PM)	5% (0.6 PM)	5% (0.6 PM)	5% (0.6 PM)	5% (0.6 PM)
Clinical Project Mgmt.	5% (0.6 PM)	5% (0.6 PM)	5% (0.6 PM)	5% (0.6 PM)	5% (0.6 PM)

This table provides a comprehensive look at both the percentage of effort and the respective person months calculated for each role over each year of the project.

3_Personnel_Costs

Personnel Budget Table for Five Years

Role	Year 1 Cost	Year 2 Cost	Year 3 Cost	Year 4 Cost	Year 5 Cost	Subtotal Cost
DCC Principal Investigator	\$22,500	\$22,500	\$22,500	\$22,500	\$22,500	\$112,500
Clinical Data Manager	\$48,000	\$48,000	\$48,000	\$48,000	\$48,000	\$240,000
Statistician	\$40,000	\$40,000	\$40,000	\$40,000	\$40,000	\$200,000
Clinical Project Manager	\$60,000	\$60,000	\$60,000	\$60,000	\$60,000	\$300,000
Business Project Manager	\$20,000	\$12,000	\$8,000	\$0	\$0	\$40,000
Ops Leader	\$10,000	\$10,000	\$10,000	\$10,000	\$10,000	\$50,000
Administrative Coordinator	\$6,000	\$6,000	\$6,000	\$6,000	\$6,000	\$30,000
Finance	\$4,000	\$4,000	\$4,000	\$4,000	\$4,000	\$20,000
Biometrics Management	\$5,000	\$5,000	\$5,000	\$5,000	\$5,000	\$25,000
Clinical Project Mgmt.	\$5,000	\$5,000	\$5,000	\$5,000	\$5,000	\$25,000
Total Costs per Year	\$220,500	\$212,500	\$208,500	\$200,500	\$200,500	\$1,042,500

Note: The individual costs were calculated by applying the respective effort allocation percentage to the annual salary (including 15% benefits) for each listed role per year.

This table will serve as the comprehensive personnel costs allocation for the budgeting process of the project under funding opportunity PAR-25-283.

3_Personnel_Justification

NIH Personnel Budget Justifications for PAR-25-283

1. DCC Principal Investigator

- **Person-months:** 1.8 PM/year for 5 years.
- **Justification:** The DCC Principal Investigator will oversee all project activities, ensuring compliance with NIH guidelines, and will also be directly involved in setting the research agenda, monitoring progress, and disseminating results. This role is critical for maintaining the integrity and direction of the research.

2. Clinical Data Manager

- **Person-months:** 7.2 PM/year for 5 years.
- **Justification:** The Clinical Data Manager is crucial for managing data collection, storage, and validation processes. This role ensures the accuracy and reliability of the research data, which is essential for achieving valid and credible research outcomes.

3. Statistician

- **Person-months:** 6.0 PM/year for 5 years.
- **Justification:** The Statistician will be responsible for all statistical analysis plans, execution of the appropriate analytical techniques, and interpretation of data. This role is vital for the rigorous evaluation of research outcomes and guiding conclusions based on the data collected.

4. Clinical Project Manager

- **Person-months:** 9.0 PM/year for 5 years.

- **Justification:** The Clinical Project Manager will coordinate the day-to-day operations of the clinical aspects of the project, ensuring milestones are met and adapting processes as necessary to meet the project's goals. This hands-on role is fundamental to the project's success.

5. **Business Project Manager**

- **Person-months:** 3.0 PM in Year 1 decreasing to 0.0 PM by Year 4.
- **Justification:** The Business Project Manager will handle project planning, budget oversight, and resource allocation. Initially critical for setting up project infrastructure and ensuring proper allocation of resources, the demand for this role decreases as the project matures and processes are established.

6. **Ops Leader**

- **Person-months:** 1.2 PM/year for 5 years.
- **Justification:** The Operations Leader will oversee logistical aspects of the project including team coordination and interfacing with external partners. This role ensures smooth operational flow and supports the administrative needs of the project.

7. **Administrative Coordinator**

- **Person-months:** 1.2 PM/year for 5 years.
- **Justification:** The Administrative Coordinator will support the project by managing communications, organizing meetings, and maintaining project records. This role is essential for ensuring efficient project administration.

8. **Finance**

- **Person-months:** 0.6 PM/year for 5 years.
- **Justification:** The Finance Officer will manage the project's budget, ensuring expenditures are within the projected scope and compliance with financial regulations, which is crucial for the fiscal responsibility of the project.

9. **Biometrics Management**

- **Person-months:** 0.6 PM/year for 5 years.
- **Justification:** This role focuses on managing the biometric devices and systems used in the study, ensuring the accurate and effective collection of biometric data which is essential for the validity of the research.

10. **Clinical Project Management**

- **Person-months:** 0.6 PM/year for 5 years.
- **Justification:** This role aids in managing clinical project components, aligning project objectives with clinical operations to ensure that clinical trials and studies are conducted efficiently and effectively.

4_Non-Personnel_Costs

Non-Personnel Budget Estimation for Funding Opportunity PAR-25-283: Innovative Mental Health Services Research (Project Duration: Not specified)

Budget Category	Total Cost (USD)
Equipment	\$0
Travel	\$0
Trainee Costs	\$0

Budget Category	Total Cost (USD)
Materials and Supplies	\$0
Site Monitoring	\$0
Data and Safety Monitoring Board	\$0
Single/Multiple IRB	\$0
Publication Costs	\$0
Consultant Services	\$0
ADP/Computer Services	\$0
Alterations and Renovations	\$0
Research Patient Care Costs	\$0
Tuition	\$0
Human Fetal Tissue	\$0
Other	\$0
Total Estimated Budget	\$0

Given the lack of the project duration information, it is not possible to compute specific total costs across all years, hence temporarily, all values are set to \$0 as a placeholder. For a detailed budget, the project period duration from the funding opportunity details would be vital.

5__Non-Personnel__Justification

The budget for funding opportunity PAR-25-283, titled “Innovative Mental Health Services Research Not Involving Clinical Trials” has been formulated. Below are the key elements:

Budget Overview:

- **Project Duration:** Not specified
- **Complexity:** Overall, the project complexity is assessed as low to medium.

Personnel Costs:

- **Roles and Efforts:** The personnel involve a range of roles from Principal Investigator, Clinical Data Manager, Statistician, and more, with effort percentages spanning from 5% to 75% across a 5-year duration.

Non-Personnel Costs:

- **Total Estimated Budget:** \$0
 - This placeholder value indicates that actual costs need to be computed based on further specifications such as project duration and detailed requirements.

Key Points:

- It is important to note that the financial planning for this project is oriented towards low complexity management, and the major focus has been given to personnel management, reflective of the significant personnel roles detailed.
- The lack of non-personal expenses might suggest that the project is primarily focusing on data-driven or theoretical work that doesn't require high external spending.

Recommendations for Completion:

1. **Determination of Project Duration:** Specific details concerning the project duration will profoundly impact the total budget and should be defined.
2. **Detailed Cost Analysis:** Once a project period is determined, a detailed cost analysis for non-personnel expenses should be undertaken considering potential needs that might arise during the project lifespan.

This budget plan serves as a fundamental framework that needs specific input related to project duration to fully flesh out a comprehensive budget. For further progress, these gaps need to be filled with accurate, specific details.