1_Funding_Opportunity_Overview

Funding Opportunity: PAR-25-283 - Innovative Mental Health Services Research Not Involving Clinical Trials (R01 Clinical Trials Not Allowed)

Opportunity Details:

- **Award Amount:** Not specified
- **Award Project Period:** Not specified
- **Link to Announcement:** PAR-25-283 Announcement

Project Complexity Assessment:

- **Regulatory:** Medium - Requires adherence to various federal regulations regarding research conduct and ethics, especially as it involves mental health services.
- **Data Collection and Management:** Medium - Data collection would require sensitive mental health data which is typically complex and requires careful handling, potentially across multiple sites.
- **Statistical Analysis and Manuscript Development:** Medium - Involves analysis of mental health data, which can be complex depending on the design of the study and the variables involved.
- **Information Technology:** Low - Likely uses standard software for data management and analysis, without deep integration of specialized IT systems.
- **Operational:** Medium - Moderate project administration is required to coordinate across different departments and manage data collection processes.
- **Financial:** Low - Budget management is relatively straightforward within this opportunity.
- **Required Budget Form:** R&R Budget Form

Budget Considerations:

Given the complexity described, the budget should account for: 1. **Staffing:** Adequate personnel to handle moderate levels of data collection, management, and analysis. This includes data analysts, database managers, and administrative support. 2. **Operational Costs:** Resources for coordination between departments, data collection tools, and administrative expenses. 3. **Regulatory Compliance:** Funds to ensure adherence to federal and institutional guidelines, including ethics clearances and ongoing compliance checks. 4. **Technology:** Budget for software tools needed for data management and analysis. 5. **Dissemination:** Costs for preparing and disseminating findings, including publications and presentations.

Further details can be elaborated by combining information from budget, personnel effort, and specific project requirements linked to this Funder's guidelines.

2_Personnel_Effort

NIH Personnel Budget Calculation for PAR-25-283

Study Duration: 5 years

Personnel Roles and Effort Allocation (% per year) & Person Months

Role	Year 1	Year 2	Year 3	Year 4	Year 5
DCC Principal Investigator	15% / 1.80 PM	15% / 1.80 PM	15% / 1.80 PM	15% / 1.80 PM	15% / 1.80 PM
Clinical Data Manager	60% / 7.20 PM	60% / 7.20 PM	60% / 7.20 PM	60% / 7.20 PM	60% / 7.20 PM
Statistician	50% / 6.00 PM	50% / 6.00 PM	50% / 6.00 PM	50% / 6.00 PM	50% / 6.00 PM
Clinical Project Manager	75% / 9.00 PM	75% / 9.00 PM	75% / 9.00 PM	75% / 9.00 PM	75% / 9.00 PM
Business Project Manager	25% / 3.00 PM	20% / 2.40 PM	15% / 1.80 PM	10% / 1.20 PM	5% / 0.60 PM
IT Operations	5% / 0.60 PM	5% / 0.60 PM	5% / 0.60 PM	5% / 0.60 PM	5% / 0.60 PM
Ops Leader	10% / 1.20 PM	10% / 1.20 PM	10% / 1.20 PM	10% / 1.20 PM	10% / 1.20 PM
Administrative Program Coordinator	10% / 1.20 PM	10% / 1.20 PM	10% / 1.20 PM	10% / 1.20 PM	10% / 1.20 PM
Finance	5% / 0.60 PM	5% / 0.60 PM	5% / 0.60 PM	5% / 0.	

3_Personnel_Costs

Comprehensive Personnel Costs Table for PAR-25-283

Role	Year 1 (USD)	Year 2 (USD)	Year 3 (USD)	Year 4 (USD)	Year 5 (USD)	Total (USD)
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	16,000	12,000	8,000	4,000	60,000
IT Operations	4,000	4,000	4,000	4,000	4,000	20,000
Ops Leader	10,000	10,000	10,000	10,000	10,000	50,000
Administrative Program Coordinator	6,000	6,000	6,000	6,000	6,000	30,000
Finance	5,000	5,000	5,000	5,000	5,000	25,000
Biometrics Management	5,000	5,000	5,000	5,000	5,000	25,000
Clinical Project Manager Management	5,000	5,000	5,000	5,000	5,000	25,000
IT Management	10,000	10,000	10,000	10,000	10,000	50,000
Total per Year	235,500	231,500	227,500	223,500	219,500	1,137,500

This table provides a detailed analysis of the personnel costs, for all roles involved in the project, calculated per year and across the full projected five-year lifespan of PAR-25-283. It incorporates the total costs for each role including their effort and benefits.

4_Personnel_Justification

Personnel Justification for PAR-25-283: Innovative Mental Health Services Research Not Involving Clinical Trials

1. DCC Principal Investigator

- **Role & Contribution:**
  - **Person-Months:** 1.80 PM per year for 5 years.
  - Justification: The principal investigator will oversee all project activities, ensuring compliance with the funding agency's guidelines, and ethical conduct of the research. They will also lead the direction of the research activities, coordinate the development of protocols, and ensure the integration of all project components.

2. Clinical Data Manager

- **Role & Contribution:**
  - **Person-Months:** 7.20 PM per year for 5 years.
  - Justification: Responsibilities include managing the data collection processes, ensuring accurate and timely data processing, and maintaining a comprehensive database. The data manager is crucial for the integrity and security of sensitive mental health data, which is fundamental for robust research outcomes.

3. Statistician

- **Role & Contribution:**
  - **Person-Months:** 6.00 PM per year for 5 years.
  - Justification: This role involves the design of statistical models, data analysis, and interpretation of data. The statistician will provide essential insights into data trends and outcomes that are critical for publishing credible, evidence-based research.

4. Clinical Project Manager

- **Role & Contribution:**
  - **Person-Months:** 9.00 PM per year for 5 years.
  - Justification: The project manager will oversee the day-to-day operations of the project, including monitoring of project milestones and coordination among different teams. This role is vital for maintaining the project timeline and ensuring the project's objectives are met.

5. Business Project Manager

- **Role & Contribution:**
  - **Person-Months:** Ranging from 3.00 PM to 0.60 PM over 5 years.
  - Justification: Focuses on the project's financial and administrative aspects, ensuring budget adherence and resource allocation align with project phases. Their effort diminishes as the project progresses and major financial frameworks are established.

6. IT Operations

- **Role & Contribution:**
  - **Person-Months:** 0.60 PM per year for 5 years.
  - Justification: Responsible for managing the project's IT requirements including data storage solutions and network management, ensuring a robust IT infrastructure to support uninterrupted research activities.

7. Ops Leader

- **Role & Contribution:**
  - **Person-Months:** 1.20 PM per year for 5 years.
  - Justification: This role is critical for overseeing operational procedures across various departments, ensuring that operational protocols are adhered to, and facilitating smooth collaboration within the team.

8. Administrative Program Coordinator

- **Role & Contribution:**
  - **Person-Months:** 1.20 PM per year for 5 years.
  - Justification: Manages administrative tasks related to the project, supporting project documentation and communication needs. This role is crucial for organizational support and efficiency.

9. Finance

- **Role & Contribution:**
  - **Person-Months:** 0.60 PM per year for 5 years.
  - Justification: Manages budget tracking and financial reporting, ensuring that expenditures remain within the allocated budget and are correctly categorized and reported according to grant requirements.

10. Biometrics Management

- **Role & Contribution:**
  - **Person-Months:** 0.60 PM per year for 5 years.
  - Justification: This role is crucial for the management of biostatistical data, including planning, execution and review of statistical analysis, delivering critical data interpretation for project validation.

11. Clinical Project Manager Management

- **Role & Contribution:**
  - **Person-Months:** 0.60 PM per year for 5 years.
  - Justification: Provides oversight to the clinical project managers, ensuring consistent adherence to clinical protocols and timelines across all project sites.

12. IT Management

- **Role & Contribution:**
  - **Person-Months:** 1.20 PM per year for 5 years.
  - Justification: Critical for the strategic planning and implementation of technological solutions that enhance research productivity and data security.

Each person's role and contribution has been tailored to ensure the project's objectives are met efficiently and effectively, supporting the overarching goal of enhancing mental health services research. This justifies the personnel allocations proposed herein.

5__Non-Personnel__Costs

Non-Personnel Budget for PAR-25-283: Innovative Mental Health Services Research

Given the complexity of the project and the expected duration, the following is an estimation of the non-personnel budget requirement for the duration of the project (assuming an average project duration of 3 years for the calculation).

Category	Total Cost for All Years (USD)
Equipment	$0
Travel	$45,000
Trainee Costs	$0
Materials and Supplies	$6,000
Site Monitoring	$12,000
Data and Safety Monitoring Board	$15,000
Single/Multiple IRB	$30,000
Publication Costs	$9,000
Consultant Services	$0
ADP/Computer Services	$0
Alterations and Renovations	$0
Research Patient Care Costs	$0
Tuition	$0
Human Fetal Tissue from elective abortions	$0
Other	$0
Total	**$117,000**

This budget table includes anticipated costs spread over the required duration and adequately addresses the typical and additional expenses associated with this kind of research project. This table will assist in the careful planning of financial resources for successful project completion.

6_Non-Personnel_Justification

Non-Personnel Budget Justification for PAR-25-283: Innovative Mental Health Services Research

Travel ($45,000) Travel expenses are allocated for conference attendance, collaboration meetings between sites, and necessary workshops. These activities are vital for disseminating findings, participating in relevant professional communities, and ensuring effective coordination across different project sites. The allotment here supports project leaders and key personnel to travel to two national conferences per year, facilitating the sharing of insights and best practices in mental health services research.

Materials and Supplies ($6,000) This category covers office supplies and other materials necessary for the day-to-day operations of the research project. Included are items such as printing of documents, specialized software for data analysis specific to mental health studies, and other miscellaneous supplies. Adequate funding in this area ensures the project team has the necessary tools to perform their tasks efficiently and effectively.

Site Monitoring ($12,000) Funds are allocated for periodic monitoring of project sites to ensure compliance with research protocols and federal regulations. This is particularly crucial in mental health research to maintain the integrity of the data and ensure the ethical handling of all study operations. These visits also allow for the on-site resolution of any issues that might arise during the project's duration.

Data and Safety Monitoring Board ($15,000) Given the sensitive nature of mental health research, an independent Data and Safety Monitoring Board (DSMB) is necessary to oversee and monitor safety throughout the study. This budget allocation covers the board members' honoraria, meeting expenses, and other administrative costs associated with the DSMB operations.

Single/Multiple IRB ($30,000) To comply with regulatory standards and ensure ethical conduct in research involving human subjects, funding is allocated for both single and multiple institutional review board (IRB) reviews. These funds cater to application, administration, and periodic review fees, which are critical in maintaining ethical oversight and compliance throughout the study duration.

Publication Costs ($9,000) This funding supports the costs associated with preparing, submitting, and publishing results in peer-reviewed journals. The availability of sufficient funds in this category is essential for disseminating research findings to the scientific community and the public, thereby contributing to broader knowledge and application of improved mental health services practices.

Each of these non-personnel budget categories has been strategically allocated to support the essential functions and requirements of the research project, ensuring adherence to quality standards and regulatory compliance while promoting effective collaboration and communication within the scientific community.