

1_Funding_Opportunity_Overview

Funding Opportunity ID: PAR-25-283

Name:

Innovative Mental Health Services Research Not Involving Clinical Trials (R01 Clinical Trials Not Allowed)

Award Amount:

The specific award amount is not mentioned.

Award Project Period:

The project period details are not specified.

Link to Opportunity Announcement:

Learn more about PAR-25-283

Project Complexity:

1. **Regulatory:** Medium - Research on mental health may involve regulations related to human subjects protection, specifically if it intersects with pharmacological or behavioral intervention studies. The need to adhere to regulations introduces moderate complexity in ensuring compliance.
2. **Data Collection and Management:** Medium - The study likely requires comprehensive data collection involving multiple mental health assessment variables, potentially across different sites. This necessitates moderate complexity due to the need for robust data handling protocols and possible coordination among various data sources.
3. **Statistical Analysis and Manuscript Development:** Medium - Expectations for detailed statistical analysis need standard, yet rigorous processes for analyzing mental health outcomes. This includes complexity due to the requirement for high data integrity and accurate interpretation of results in the context of mental health research.
4. **Information Technology:** Low - General IT support is necessary for managing data and facilitating communication, but does not involve advanced or highly specialized systems. This results in lower complexity related to IT infrastructure.
5. **Operational:** Medium - Managing operations across potentially multiple research sites and ensuring smooth data flow can be challenging. This entails a moderate level of complexity in project administration and participant data management.
6. **Financial:** Low - Given that this is an 'R01' application and the description suggests a straightforward approach without extensive subcontracting or consortium arrangements, financial management complexity is minimal. The budget involves routine planning and allocation.

Required Budget Form:

The R&R Budget Form is required, which needs detailed financial information to accompany the application for this grant opportunity.

2__Personnel__Effort

Below is the table displaying both the yearly effort allocation percentages and the corresponding calculated person months for the different roles involved in the NIH research project under funding opportunity PAR-25-283. The project's complexity and required roles have been considered to estimate these values.

Role	Year 1 Effort (%)	Year 1 Person Months	Year 2 Effort (%)	Year 2 Person Months	Year 3 Effort (%)	Year 3 Person Months
DCC Principal Investigator	15%	1.8	15%	1.8	15%	1.8
DCC Co-Principal Investigator	15%	1.8	15%	1.8	15%	1.8
Clinical Data Manager	60%	7.2	60%	7.2	60%	7.2
Statistician	50%	6.0	50%	6.0	50%	6.0
Clinical Project Manager	75%	9.0	75%	9.0	75%	9.0
Business Project Manager	25%	3.0	5%	0.6	0%	0.0
IT Operations	5%	0.6	5%	0.6	5%	0.6
Ops Leader	10%	1.2	10%	1.2	10%	1.2
Administrative Program Coordinator	10%	1.2	10%	1.2	10%	1.2
Regulatory and Quality Assurance Manager	5%	0.6	5%	0.6	5%	0.6
Finance	5%	0.6	5%	0.6	5%	0.6
Biometrics Management	5%	0.6	5%	0.6	5%	0.6
Clinical Project Manager Management	5%	0.6	5%	0.6	5%	0.6

This table provides the necessary information to understand the personnel budget structure in all phases of the project. Adjustments to the percentage of time dedicated depend on the specific requirements of each project year.

3__Personnel__Justification

As part of my role, I will now generate a comprehensive justification summary for each role involved in the NIH project under the funding opportunity PAR-25-283. Here is the justification for each personnel member based on their roles and effort commitment throughout the project period:

Personnel Justification

1. DCC Principal Investigator

- **Effort Allocation:** 1.8 person-months per year for 3 years.
- **Role Justification:** The Principal Investigator will oversee the entire project, ensuring alignment with the funding objectives of innovative mental health services research. This includes supervising and collaborating with the research team, ensuring adherence to regulations, and leading the submission of required reports. Their continued engagement is critical for strategic direction and high-level decision-making.

2. DCC Co-Principal Investigator

- **Effort Allocation:** 1.8 person-months per year for 3 years.
- **Role Justification:** The Co-Principal Investigator will work closely with the Principal Investigator to manage the research project. Responsibilities include assisting in project management, coordinating with different stakeholders, and supervising subordinate staff to ensure smooth operation and compliance with the study protocol.

3. Clinical Data Manager

- **Effort Allocation:** 7.2 person-months per year for 3 years.
- **Role Justification:** The Clinical Data Manager is key to managing the data collection, integration, and cleaning processes. Their expertise is essential in ensuring data accuracy and reliability, which is critical for the validity of the research findings in mental health services.

4. Statistician

- **Effort Allocation:** 6.0 person-months per year for 3 years.
- **Role Justification:** The Statistician will be responsible for all statistical analysis tasks, including developing analysis plans, performing statistical analysis, and interpreting data results. Their skills are vital for ensuring that the conclusions drawn from the research are statistically robust.

5. Clinical Project Manager

- **Effort Allocation:** 9.0 person-months per year for 3 years.
- **Role Justification:** Primarily responsible for overseeing the day-to-day operations of clinical research activities, the Clinical Project Manager ensures that the project adheres to regulatory standards and timelines. Their involvement is crucial for coordinating clinical trials and managing research participants.

6. Business Project Manager

- **Effort Allocation:** From 3.0 person-months in Year 1 to 0.6 in Year 2.
- **Role Justification:** The Business Project Manager will handle the project's financial operations and resource allocation in the initial phases. This role is critical in the setup and early management stages, ensuring that the project remains within budget and resources are used efficiently.

7. IT Operations

- **Effort Allocation:** 0.6 person-months per year for 3 years.
- **Role Justification:** Supports the technical infrastructure required for the project, including software and hardware management crucial for data collection and analysis. Continuous IT support ensures that technical issues do not hinder the project's progress.

8. Ops Leader

- **Effort Allocation:** 1.2 person-months per year for 3 years.
- **Role Justification:** Coordinates operational strategies and ensures optimal resource utilization across project sites. This role is essential for maintaining efficient workflow and supporting the project management team.

9. Administrative Program Coordinator

- **Effort Allocation:** 1.2 person-months per year for 3 years.
- **Role Justification:** Manages administrative tasks and supports project logistics, facilitating effective communication between project teams and external partners.

10. Regulatory and Quality Assurance Manager

- **Effort Allocation:** 0.6 person-months per year for 3 years.
- **Role Justification:** Ensures compliance with applicable regulatory requirements and oversees quality assurance of the project. This role is crucial for maintaining ethical standards and regulatory compliance in research.

11. Finance

- **Effort Allocation:** 0.6 person-months per year for 3 years.
- **Role Justification:** Manages financial aspects including budgeting, expense tracking, and financial reporting. Critical for ensuring fiscal responsibility and adherence to funding guidelines.

12. Biometrics Management

- **Effort Allocation:** 0.6 person-months per year for 3 years.
- **Role Justification:** Oversees the collection and analysis of biometric data, important for understanding the impact of mental health interventions.

13. Clinical Project Manager Management

- **Effort Allocation:** 0.6 person-months per year for 3 years.
- **Role Justification:** Provides additional managerial support and supervision, ensuring that clinical operations meet project timelines and objectives effectively.

These justifications reflect the diverse roles and their critical contributions to ensuring the success of the project compliant with NIH stipulations for innovative mental health services research.

4_Non-Personnel_Costs

Based on the complexity and requirements of funding opportunity PAR-25-283, here is the estimated total cost per category for the entire duration of the project:

Category	Total Cost (All project years \$)
Equipment	\$10,000
Travel	\$15,000
Trainee Costs	\$0
Materials and Supplies	\$20,000
Site Monitoring	\$25,000
Data and Safety Monitoring Board	\$20,000
Single/Multiple IRB	\$15,000
Publication Costs	\$10,000
Consultant Services	\$30,000
ADP/Computer Services	\$5,000
Alterations and Renovations	\$0
Research Patient Care Costs	\$0
Tuition	\$0
Human Fetal Tissue from elective abortions	\$0
Other	\$5,000

These estimates are based on a medium complexity project with a focus on mental health services research, involving standard regulatory, data management, operational practices, and statistical processes. This budget structure supports the overall research needs and compliance with NIH requirements for this specific type of project.

5_Non-Personnel_Justification

Non-Personnel Budget Justification for PAR-25-283

Equipment (\$10,000) The budget allocates \$10,000 to equipment essential for research activities. This sum covers costs linked to purchasing specialty research tools and software that are imperative for collecting and analyzing data on mental health. The inclusion of these resources significantly enhances our capability to conduct sophisticated analyses, necessary for high-impact results in the field of mental health services research.

Travel (\$15,000) The allocated \$15,000 for travel covers the expenses for attending significant conferences and meetings, as well as travel between collaborating sites. This is integral to facilitating collaboration among project members, engaging with the wider research community, and disseminating research findings effectively.

Materials and Supplies (\$20,000) A total of \$20,000 is set aside for materials and supplies. This encompasses all tangible items necessary for daily research activities including but not limited to laboratory consumables, books, and specialized software licenses. These materials support the robust execution of the project's research methodologies.

Site Monitoring (\$25,000) The project allocates \$25,000 for site monitoring, ensuring adherence to study protocols and maintaining high standards of data integrity and compliance. This is crucial in upholding the quality and reliability of the findings, particularly in a multi-site project involving diverse settings and populations.

Data and Safety Monitoring Board (\$20,000) An allocation of \$20,000 for the Data and Safety Monitoring Board (DSMB) underlines our commitment to participant safety and data reliability. The DSMB will oversee the study operations by reviewing safety data from trials to ensure that health risks are minimized and study integrity is not compromised.

Single/Multiple IRB (\$15,000) The budget includes \$15,000 for Single/Multiple Institutional Review Board (IRB) expenses. This ensures the ethical management and oversight of the study, which is especially important for research involving human subjects, as it involves detailed scrutiny and continuous oversight throughout the project lifecycle.

Publication Costs (\$10,000) Publication costs summing to \$10,000 are designated for the dissemination of findings through peer-reviewed journals and presentations. This element of the budget aids in the broad distribution of the project outcomes, contributing to the field's existing body of knowledge and influencing future research directions.

Consultant Services (\$30,000) Consultant services are budgeted at \$30,000, providing funds for expert advice in areas such as statistical analysis, clinical practices, and regulatory compliance. These consultants are critical to fine-tuning our research methodology and ensuring all procedures meet the highest standards.

ADP/Computer Services (\$5,000) A budget of \$5,000 is set for ADP/computer services to manage and support data processing needs. Given the data-intensive nature of the project, these services will support data entries, processing, and secure storage, ensuring rapid accessibility and data integrity.

Other (\$5,000) Finally, an additional \$5,000 is reserved for unforeseen costs that are not accommodated in other categories but that may arise during the project lifecycle. This budgetary cushion ensures flexibility and preparedness for unexpected expenses.

Equipment through Other categories support the comprehensive operational and strategic requirements of this project, directly impacting the efficiency and effectiveness of the research conducted under PAR-25-283. The coverage within these budget items ensures adequate resourcing to address all anticipated needs and unexpected challenges, thereby maximizing the potential for successful outcomes.