1_Funding_Opportunity_Overview

Study Complexity Assessment and Budget Requirements for PAR-25-283

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

Project Complexity Summary:
1. **Regulatory**: Low - No significant regulatory requirements as it does not involve human subjects or clinical trials.

2. **Data Collection and Management**: Medium
   - Data collection methods for mental health services research, typically with limited participating sites.
3. **Statistical Analysis and Manuscript Development**: Medium
   - Standard statistical analysis along with development of manuscripts based on research findings.
4. **Information Technology**: Low
   - Routine data management software likely sufficient, with minimal IT monitoring and maintenance needed.
5. **Operational**: Low
   - Limited administrative effort for project management due to the absence of clinical trials and fewer stakeholders involved.
6. **Financial**: Low
   - Straightforward budget management without complex cost management needs.

Budget Form Required

- **PHS 398 Modular Budget Form** is required for this opportunity, as the application does not involve human fetal tissue from elective abortions nor does it exceed $250,000 in direct costs.

For further steps in generating the budget, please specify more detailed needs or refer to the guidelines provided in the funding opportunity link: NIH Guide for PAR-25-283.

2_Personnel_Effort

NIH Personnel Budget with Person-Months for PAR-25-283

Here's the detailed personnel budget including effort allocations and person-months for the required team roles, assuming a 5-year project period:

Role	Year 1	Year 2	Year 3	Year 4	Year 5
DCC Principal Investigator	15% (1.8)	15% (1.8)	15% (1.8)	15% (1.8)	15% (1.8)
Clinical Data Manager	60% (7.2)	60% (7.2)	60% (7.2)	60% (7.2)	60% (7.2)
Statistician	50% (6.0)	50% (6.0)	50% (6.0)	50% (6.0)	50% (6.0)
Clinical Project Manager	75% (9.0)	75% (9.0)	75% (9.0)	75% (9.0)	75% (9.0)
Business Project Manager	25% (3.0)	20% (2.4)	10% (1.2)	0% (0.0)	0% (0.0)
IT Operations	10% (1.2)	10% (1.2)	10% (1.2)	10% (1.2)	10% (1.2)

Role	Year 1	Year 2	Year 3	Year 4	Year 5
Ops Leader	10% (1.2)	10% (1.2)	10% (1.2)	10% (1.2)	10% (1.2)
Administrative Program Coordinator	10% (1.2)	10% (1.2)	10% (1.2)	10% (1.2)	10% (1.2)
Finance	5% (0.6)	5% (0.6)	5% (0.6)	5% (0.6)	5% (0.6)
Biometrics Management	5% (0.6)	5% (0.6)	5% (0.6)		

3_Personnel_Justification

Personnel Justification for PAR-25-283

Project Role and Justification of Effort:

1. **DCC Principal Investigator (PI)**:
   - **Effort**: 15% annually
   - **Justification**: The PI will oversee all project operations, ensuring compliance with regulatory standards and alignment with the funding opportunity's objectives. The proposed effort reflects the PI's critical role in guiding the project's strategic direction, supervising the research team, and maintaining stakeholder relationships.
2. **Clinical Data Manager**:
   - **Effort**: 60% annually
   - **Justification**: This role is pivotal for managing the collection, validation, and analysis of data throughout the project. Given the complexity and volume of data associated with mental health services research, the high percentage of effort is justified to ensure data integrity and timely reporting.
3. **Statistician**:
   - **Effort**: 50% annually
   - **Justification**: Responsible for the statistical analysis of study data, critical for deriving reliable findings and supporting the publication of results in scientific journals. This effort ensures rigorous data analysis and interpretation, which is central to the project's success.
4. **Clinical Project Manager**:
   - **Effort**: 75% annually
   - **Justification**: Takes charge of managing the clinical operations and coordination of the project across various sites. This role's effort is warranted by the substantial coordination and operational oversight required to maintain project timelines and quality standards.
5. **Business Project Manager**:
   - **Effort**: Gradually reduces from 25% in Year 1 to 0% in Year 5
   - **Justification**: Essential during the initial setup and scaling down as the project structure and processes become established. This transition reflects the project's shifting needs from setup to maintenance.
6. **IT Operations**:
   - **Effort**: 10% annually
   - **Justification**: Ensures that all data systems are operational, secure, and efficient. Involvement is consistent and crucial throughout the project to support the technology needs of the data management and analysis teams.

7. **Ops Leader, Administrative Program Coordinator, Finance, Biometrics Management, Clinical Project Manager Management, IT Management**:
   - **Effort**: 5-10% annually
   - **Justification**: These roles provide essential support and oversight, ensuring that the project adheres to budget, policy, and operational requirements. Each role's effort is key to the smooth and compliant execution of the project activities.

This personnel justification outlines the necessity and rationale for each proposed effort percentage, ensuring alignment with the project's objectives and the strategic management of its resources.

4_Non-Personnel_Costs

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

The following are the estimated costs for each non-personnel category over the entire duration of the project for funding opportunity PAR-25-283:

Category	Total Cost (All Project Years $)
Equipment	$15,000
Travel	$8,000
Trainee Costs	$0
Materials and Supplies	$5,000
Site Monitoring	$12,000
Data and Safety Monitoring Board	$10,000
Single/Multiple IRB	$4,000
Publication Costs	$6,000
Consultant Services	$10,000
ADP/Computer Services	$3,000
Alterations and Renovations	$2,000
Research Patient Care Costs	$0
Tuition	$0
Human Fetal Tissue from elective abortions	$0
Other	$5,000

Note: The cost estimates provided above consider the assessment of project complexity and other requirements as outlined by the funding opportunity. For itemized details or specific justifications, additional information such as the number of research participants, the number of trips planned (for travel section), or the specifics about equipment and licensing for software (for ADP/computer services) would be required.

5_Non-Personnel_Justification

Non-Personnel Budget Justification for PAR-25-283

Here is a detailed justification for each non-personnel budget category for the funding opportunity PAR-25-283, based on the impact of each category on the study.

Equipment - $15,000 Justification: The allocated budget for equipment includes essential research tools and technology that are necessary for the collection, storage, and analysis of data specific to mental health services research. These items may include specialized software, hardware, and other related technologies that ensure precise and reliable data collection and analysis. The investment in high-quality equipment enhances the accuracy and efficiency of the research conducted under this project.

Travel - $8,000 Justification: Funds allocated for travel cover the expenses for attending crucial conferences, training sessions, and meetings with stakeholders involved in mental health services research. This budget line enables the team to engage with the wider research community, stay updated with the latest developments in the field, and disseminate findings effectively. Networking and collaboration through these travels are vital for maximizing the impact of the research and encouraging multi-site coordination.

Materials and Supplies - $5,000 Justification: This budget covers all necessary materials and supplies that are required throughout the project. This includes stationary, minor equipment, lab supplies, and other expendables that support the day-to-day research activities. Maintaining a well-stocked inventory of these supplies ensures that the project remains productive and meets its timelines without delays.

Site Monitoring - $12,000 Justification: The funds will support the costs associated with the periodic monitoring of site activities to ensure compliance with study protocols and regulations. This category ensures that data collection methodologies are consistent across different sites and that study standards are upheld throughout the project duration. Effective site monitoring is crucial for guaranteeing the validation and integrity of the research data.

Data and Safety Monitoring Board - $10,000 Justification: Allocations to this category cover expenses related to the operations of a Data and Safety Monitoring Board (DSMB). This board is essential for overseeing the safety of data collection processes and the welfare of any participants indirectly involved through data usage. The DSMB plays a critical role in ensuring that the study adheres to the highest ethical standards and helps mitigate any risks associated with the research activities.

Single/Multiple IRB - $4,000 Justification: The budget supports costs involved with the Institutional Review Board(s) (IRB) review and approval processes, which are mandatory for ensuring all research practices are ethical and that the privacy and rights of individuals (whose data may be used) are protected. Efficient functioning of IRB(s) is crucial for the validation and legitimization of the research study.

Publication Costs - $6,000 Justification: This allocation aids in the manuscript preparation, submission, and publishing processes associated with disseminating research findings. The ability to publish in high-impact journals is essential for sharing valuable insights gained during the project, which can influence future practices and policies in mental health services research.

Consultant Services - $10,000 Justification: Funding for consultant services involves engaging experts who provide specialized knowledge or skills that complement the existing team's capabilities. Consultants might include statisticians, subject matter experts, or other professionals whose expertise can significantly bolster the project's output and success.

ADP/Computer Services - $3,000 Justification: This budget line provides for advanced data processing and computer services that are essential for data analysis, storage, and security. Investments in robust IT support ensure that data management is seamless and adheres to best practices in data security.

Alterations and Renovations - $2,000 Justification: The budget supports minor modifications or enhancements of the physical research environment to make it more suited for the specific needs of the project. This may include ergonomic improvements for workstations or adjustments to lab spaces, which can significantly enhance the efficacy and safety of the research settings.

Other - $5,000 Justification: This category includes miscellaneous costs that do not fit neatly into other categories but are essential for the smooth execution and administration of the project. It provides flexible funding to address unforeseen expenses or unique needs that may arise during the project lifecycle.

Each category has been assessed and justified based on its necessity and impact on the success and integrity of the research project. These budget allocations are essential for ensuring that the project is equipped with the necessary resources to efficiently meet its objectives and contribute meaningful advancements in mental health services research.