

## 1\_Funding\_Opportunity\_Overview

### Funding Opportunity Overview

**Opportunity ID:** PAR-25-283 **Name:** Innovative Mental Health Services Research Not Involving Clinical Trials (R01 Clinical Trials Not Allowed)  
**Award Amount:** (Information not provided in the context) **Award Project Period:** (Information not provided in the context) **Link to Opportunity Announcement:** PAR-25-283 Announcement

### Project Complexity

1. **Regulatory:** Low - The project likely involves standard research regulations without a focus on high-risk areas or sensitive populations, as it does not involve clinical trials.
2. **Data Collection and Management:** Medium - Involves mental health service research which may require collecting moderate data elements, but likely not as extensive as in clinical trials.
3. **Statistical Analysis and Manuscript Development:** Medium - Involves standard analysis techniques since it does not use clinical trials but still needs thorough analysis relevant to mental health.
4. **Information Technology:** Low - Routine IT support likely required, with no indication of complex software or systems involved.
5. **Operational:** Medium - Moderate project administration efforts will be required, particularly in coordinating research activities across various settings.
6. **Financial:** Low - Budget management is likely straightforward since it does not involve complex grant arrangements.

### Required Budget Form

Since the opportunity is not a research grant or cooperative agreement, the required budget form is the **detailed form (R&R Budget Form)**.

## 2\_Personnel\_Effort

To facilitate the completion of the budget form for PAR-25-283, “Innovative Mental Health Services Research Not Involving Clinical Trials,” we’ll specify the effort allocation and calculate person-months for critical personnel roles required over a presumed five-year project period.

### Personnel Effort and Person-Months Breakdown:

Below, I will assume a standard project structure typically fitting the outlined complexity and duration of this opportunity.

Roles	Year 1	Year 2	Year 3	Year 4	Year 5
<b>DCC Principal Investigator</b>	15% (1.8 months)	15% (1.8 months)	15% (1.8 months)	15% (1.8 months)	15% (1.8 months)
<b>Clinical Data Manager</b>	60% (7.2 months)	60% (7.2 months)	60% (7.2 months)	60% (7.2 months)	60% (7.2 months)
<b>Statistician</b>	50% (6 months)	50% (6 months)	50% (6 months)	50% (6 months)	50% (6 months)
<b>Clinical Project Manager</b>	75% (9 months)	75% (9 months)	75% (9 months)	75% (9 months)	75% (9 months)
<b>Business Project Manager</b>	25% (3 months)	5% (0.6 months)	0% (0 months)	0% (0 months)	0% (0 months)
<b>IT Operations</b>	0% (0 months)	0% (0 months)	0% (0 months)	0% (0 months)	0% (0 months)

Roles	Year 1	Year 2	Year 3	Year 4	Year 5
<b>Ops Leader</b>	10% (1.2 months)	10% (1.2 months)	10% (1.2 months)	10% (1.2 months)	10% (1.2 months)
<b>Administrative Program Coord.</b>	10% (1.2 months)	10% (1.2 months)	10% (1.2 months)	10% (1.2 months)	10% (1.2 months)
<b>Finance</b>	5% (0.				

### 3\_Personnel\_Costs

#### Personnel Costs Calculation

Below is the calculation of the total personnel costs for each role over five years, incorporating the assumed salary, employee benefit rate at 15%, and the effort percentages provided.

#### Personnel Costs Table

Roles	Year 1	Year 2	Year 3	Year 4	Year 5
<b>DCC Principal Investigator</b>	\$25,875	\$25,875	\$25,875	\$25,875	\$25,875
<b>Clinical Data Manager</b>	\$69,120	\$69,120	\$69,120	\$69,120	\$69,120
<b>Statistician</b>	\$57,600	\$57,600	\$57,600	\$57,600	\$57,600
<b>Clinical Project Manager</b>	\$86,400	\$86,400	\$86,400	\$86,400	\$86,400
<b>Business Project Manager</b>	\$17,280	\$3,456	\$0	\$0	\$0
<b>IT Operations</b>	\$0	\$0	\$0	\$0	\$0
<b>Ops Leader</b>	\$13,800	\$13,800	\$13,800	\$13,800	\$13,800
<b>Administrative Program Coord.</b>	\$8,280	\$8,280	\$8,280	\$8,280	\$8,280
<b>Finance</b>	\$5,520	\$5,520	\$5,520	\$5,520	\$5,520
<b>Biometrics Management</b>	\$6,900	\$6,900	\$6,900	\$6,900	\$6,900
<b>Clinical Project Mgmt Mgmt.</b>	\$6,900	\$6,900	\$6,900	\$6,900	\$6,900

**Note:** Each value above includes the salary cost augmented by 15% for benefits. The calculations are based on the provided effort percentages converted from the effort allocations.

This table summarizes the financial requirement for each personnel role throughout the project duration, aiding in a detailed budgetary planning for the NIH grant submission.

## 4\_Personnel\_Justification

### NIH Personnel Budget Justification for PAR-25-283

The following justifications correspond with the personnel effort and responsibilities outlined for the project funded under PAR-25-283, “Innovative Mental Health Services Research Not Involving Clinical Trials”. These roles are critical to the project’s success over its planned 5-year duration.

#### 1. DCC Principal Investigator

- **Effort:** 9 person-months total over 5 years (1.8 months per year)
- **Justification:** The DCC Principal Investigator will oversee all project management activities, ensure adherence to NIH guidelines, and provide oversight on all research outcomes and deliverables throughout the project duration. Their leadership is crucial for maintaining the integrity and direction of the research.

#### 2. Clinical Data Manager

- **Effort:** 36 person-months total over 5 years (7.2 months per year)
- **Justification:** The Clinical Data Manager will handle comprehensive data management tasks including data collection, quality checks, and database management. This role is central to the project’s ability to generate reliable data for analysis and ensure that the outcomes of the research are based on accurate and high-integrity data systems.

#### 3. Statistician

- **Effort:** 30 person-months total over 5 years (6 months per year)
- **Justification:** The Statistician will design and execute statistical analyses and ensure that the research data are interpreted correctly. This role is essential for the robust analysis of data which will contribute to the validity of the research findings.

#### 4. Clinical Project Manager

- **Effort:** 45 person-months total over 5 years (9 months per year)
- **Justification:** The Clinical Project Manager will be responsible for the coordination of all clinical research activities, compliance with ethical standards, and liaison with clinical sites. Their work is crucial for the smooth execution of the project’s operations and adherence to the timeline.

#### 5. Business Project Manager (Year 1 only)

- **Effort:** 3.6 person-months total over the first year
- **Justification:** The Business Project Manager will oversee the initial setup of project operations, including establishing the project’s framework, coordinating initial team efforts, and ensuring a standardized approach across all operational fronts. This role is vital in the early phase for setting up the foundations of the projec...

## 5\_Non-Personnel\_Costs

### Total Estimated Budget for PAR-25-283

Given the details of the project, here is the estimated budget for necessary categories based on an assumed project duration of 5 years. Project-specific details like number of sites were not provided, so averages are used.

Category	Total Cost for 5 Years (USD)
Equipment	0
Travel	85,000
Trainee Costs	0
Materials and Supplies	10,000
Site Monitoring	22,500
Data and Safety Monitoring Board	27,500
Single/Multiple IRB	62,500
Publication Costs	17,500
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
<b>Total</b>	<b>225,000</b>

This table represents the total forecasted non-personnel costs for the duration of the project under the provided NIH guidelines and project complexity. The values listed above average per year expenditures, multiplied by 5 to reflect the total budget across the entire project lifespan. This assumes the average end of given ranges and typical expenditures for a project of medium complexity in mental health research services as described.

## 6\_Non-Personnel\_Justification

### NIH Non-Personnel Budget Justification for PAR-25-283

The following is a justification for each non-personnel budget category for the project funded under PAR-25-283, “Innovative Mental Health Services Research Not Involving Clinical Trials”. The detailed narrative explains the necessity and estimation of costs associated with each category over the planned 5-year project period.

#### 1. Equipment

- **Total Cost:** \$0
- **Justification:** No additional equipment purchase is necessary for this project, as existing institutional resources are sufficient to support all research activities.

#### 2. Travel

- **Total Cost:** \$85,000

- **Justification:** Funds will cover the costs for attending key research conferences and meetings essential for staying updated with the latest research and best practices in mental health services. This includes travel for the principal investigator and key project staff to four conferences per year, estimated at approximately \$4,250 per conference.

### 3. Trainee Costs

- **Total Cost:** \$0
- **Justification:** No trainee costs are required since the project does not involve any training components.

### 4. Materials and Supplies

- **Total Cost:** \$10,000
- **Justification:** This budget will cover necessary supplies such as software licenses, office supplies, and other consumables needed for daily operations of the research. These materials are critical for data collection, storage, and general project management.

### 5. Site Monitoring

- **Total Cost:** \$22,500
- **Justification:** Ensuring quality and integrity of the research sites, funds are allocated to conduct annual site visits and reviews over the project duration. This ensures compliance with study protocols and effective data collection procedures.

### 6. Data and Safety Monitoring Board

- **Total Cost:** \$27,500
- **Justification:** Although the study does not involve clinical trials, the establishment of a Data and Safety Monitoring Board (DSMB) is critical to oversee the data management and ensure participant safety in line with ethical research practices. This budget covers meetings and compensation for board members.

### 7. Single/Multiple IRB

- **Total Cost:** \$62,500
- **Justification:** Funds are allocated for the ethical review and oversight provided by an Institutional Review Board (IRB), facilitating multiple site approvals and continuous monitoring throughout the project lifecycle.

### 8. Publication Costs

- **Total Cost:** \$17,500
- **Justification:** The budget includes costs related to the publication of findings in peer-reviewed journals, ensuring wide dissemination of the research results which is key for advancing public health strategies in mental health services.

#### 9. Consultant Services

- **Total Cost:** \$0
- **Justification:** No consultant services are required as all necessary expertise is available within the project team.

#### 10. ADP/Computer Services

- **Total Cost:** \$0
- **Justification:** There are no additional costs for automated data processing or computer services as existing institutional IT resources are adequate.

#### 11. Alterations and Renovations

- **Total Cost:** \$0
- **Justification:** No alterations or renovations are necessary for project execution.

#### 12. Research Patient Care Costs

- **Total Cost:** \$0
- **Justification:** This project does not involve direct patient care costs as it is focused on services research without clinical trials.

#### 13. Tuition

- **Total Cost:** \$0
- **Justification:** No tuition costs are included as there are no educational components requiring such expenses in this project.

#### 14. Human Fetal Tissue from elective abortions

- **Total Cost:** \$0
- **Justification:** This category is not applicable to the nature of this research project.

#### 15. Other

- **Total Cost:** \$0
- **Justification:** All necessary budgetary considerations have been covered in the specified categories with no additional unspecified costs anticipated.

The budget plan ensures comprehensive financial coverage for all essential aspects of the project, enhancing the project's success potential in advancing mental health services research.