1. **Specific Aims [1 page]**

# Candidate [1 page]

*The following sections should be included:*

## Background

## Career Goals and Objectives

# Career Development and Mentoring Plan [1-2 pages]

*The following sections should be included:*

## Career Development Plan (including timeline)

## Required Training in Responsible Conduct of Research

# Research Plan [3 pages]

*The following sections should be included:*

## Background/Significance

## Innovation

## Approach

## Sample Size/Power

## Statistical Analysis

## Timeline

### Plan for data and safety monitoring (biomedical and behavioral intervention studies only)

# References

# Biosketch - Candidate [< 5 pages]

*Please use the General Biographical Sketch Format Page\*\* from the* [*SF424 (R&R) Application and Electronic Submission Information*](https://grants.nih.gov/grants/forms/biosketch.htm) *page on the NIH website (updated by NIH 10/2021).*

# Statement by Mentors, Collaborators

*Statements should be from individuals who will be working directly with the applicant on the proposed project.*

# Institutional Letter of Support/Intent [1 page]

*A letter from the applicant’s Department Chair (or similar representative) guaranteeing departmental commitment to ensuring the applicant will be provided the required protected time.*

# Budget and Budget Justification

|  |  |
| --- | --- |
| Program Director/Principal Investigator (Last, First, Middle): |       |
|  |
| DETAILED BUDGET FOR INITIAL BUDGET PERIODDIRECT COSTS ONLY | FROM | THROUGH |
|       |       |

 List PERSONNEL *(Applicant organization only)* Use Cal, Acad, or Summer to Enter Months Devoted to Project

 Enter Dollar Amounts Requested *(omit cents)* for Salary Requested and Fringe Benefits

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| NAME | ROLE ONPROJECT | Cal.Mnths | Acad.Mnths | SummerMnths | INST.BASESALARY | SALARYREQUESTED | FRINGEBENEFITS | TOTAL |
|       | PD/PI |       |       |       |       |       |       |       |
|       |       |       |       |       |       |       |       |       |
|       |       |       |       |       |       |       |       |       |
|       |       |       |       |       |       |       |       |       |
|       |       |       |       |       |       |       |       |       |
|       |       |       |       |       |       |       |       |       |
|       |       |       |       |       |       |       |       |       |
| SUBTOTALS |       |       |       |
| CONSULTANT COSTS      |       |
| EQUIPMENT *(Itemize)*      |       |
| SUPPLIES *(Itemize by category)*      |       |
| TRAVEL      |       |
| INPATIENT CARE COSTS       |       |
| OUTPATIENT CARE COSTS       |       |
| ALTERATIONS AND RENOVATIONS *(Itemize by category)*      |       |
| OTHER EXPENSES *(Itemize by category)*      |       |
| CONSORTIUM/CONTRACTUAL COSTS | DIRECT COSTS |       |
| SUBTOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD *(Item 7a, Face Page)* | $ |       |
| CONSORTIUM/CONTRACTUAL COSTS | FACILITIES AND ADMINISTRATIVE COSTS |       |
| TOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD  | $ |       |

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## Budget Justification

**Project Title**

**Personnel**

Personnel salary support and role~~s~~ should be specified and justified.

**Consultants**

Any consultant’s funding and role~~s~~ should be specified and justified.

**Equipment**

Itemize.

**Supplies**

Itemize by categories. Include expenses such as user fees and animal costs and per diem. If there will be an unequal distribution of expenses between years of the award period, identify and justify.

**Travel Expenses**

Specify by travel destination and purpose.

**Research In/Patient Care Costs**

**Research Out/Patient Care Costs**

**Sharing**

Indicate any cost sharing involved in this project.

**Alterations and Renovations**

Indicate any cost sharing involved in this project.

**Other Expenses**

Indicate any cost sharing involved in this project.

**Total Award Requested**:

## Budget and Justification Instructions [Do not include in final submission]

### **Personnel**

**Name.** Starting with the PI(s), list the names of all applicant organization employees who are involved on the project during the initial budget period, regardless of whether a salary is requested. Include all collaborating investigators, individuals in training, and support staff.

**Role on Project.** Identify the role of each individual listed on the project. Describe their specific functions under Justification. Provide budget narrative for ALL personnel by position, role, and level of effort using person months (calendar, academic and/or summer). This includes any “to-be-appointed” positions.

**Months Devoted to Project.** Enter the number of months devoted to the project. Three columns are provided depending on the type of appointment being reflected: academic, calendar, and/or summer months. Individuals may have consecutive appointments within a calendar year, for example for an academic period and a summer period. In this case, each appointment should be identified separately using the corresponding column.

If effort does not change throughout the year, use only the calendar months column. If effort varies between academic and summer months, leave the calendar months column blank and use only the academic and summer month’s columns. In cases where no contractual appointment exists with the applicant organization and salary is requested, enter the number of months for the requested period.

**Salary Requested.** Regardless of the number of months being devoted to the project, indicate only the amount of salary being requested for this budget period for each individual listed.

The specific role in the project should be identified. If partial salary is requested, indicate the percentage and source of remaining support (e.g., departmental). Salaries cannot exceed the current NIH salary cap amount.

**Consultant Costs**

Any consultant’s funding and role~~s~~ should be specified and justified. Whether or not costs are involved, provide the names and organizational affiliations of all consultants, other than those involved in consortium/contractual arrangements. Include consultant physicians in connection with patient care and persons who are confirmed to serve on external monitoring or advisory committees. Describe the services to be performed on under “Justification.” Include the number of days of anticipated consultation, the expected rate of compensation, travel, per diem, and other related costs. ***Note:*** A consultant is defined as “an individual hired to perform professional, short-term services.” Consultants differ from Consortiums (Subcontracts) in that they may provide advice or services, but do not make decisions for the direction of the research. If the relationship involves more than completing specific, well-defined, limited scope tasks, then a subcontract should be pursued with the individual’s institution.

#### **Equipment**

List each item of equipment with amount requested separately, and justify each purchase.

#### **Supplies**

Itemize supplies in separate categories, such as glassware, chemicals, radioisotopes, etc. Categories in amounts less than $1,000 do not have to be itemized. If animals are to be purchased, state the species and the number to be used.

#### **Travel**

Itemize travel requests and justify. Provide the purpose and destination of each trip and the number of individuals for whom funds are requested.

#### **Research Patient Care Costs**

If research inpatient and/or research outpatient costs are requested for research with human subjects, provide the names of any hospitals and/or clinics and the amounts requested for each.

State whether each hospital or clinic has a currently effective DHHS-negotiated research patient care rate agreement and, if not, what basis is used for calculating costs. If an applicant does not have a DHHS-negotiated rate, a provisional rate can be approved. Indicate, in detail, the basis for estimating costs in this category, including the number of patient days, estimated cost per day, and cost per test or treatment. If both research inpatient and outpatient costs are requested, provide information for each separately. If multiple sites are to be used, provide detailed information by site.

Include information regarding projected patient accrual for the project/budget periods and relate this information to the budget request for patient care costs. If patient accrual is anticipated to be lower at the start or during the course of the project, plan budget(s) accordingly.

Provide specific information regarding anticipated sources of Other Support for research patient care costs, e.g., third party recovery or pharmaceutical companies. Include any potential or expected utilization of CTSI Resources.

#### **Other Expenses**

Itemize any other expenses by category and unit cost. These might include animal maintenance (unit care costs and number of care days), participation incentives, donor fees, publication costs, computer charges, rentals and leases, equipment maintenance, service contracts.

|  |  |
| --- | --- |
| Program Director/Principal Investigator (Last, First, Middle): |       |
|  |
| BUDGET FOR ENTIRE PROPOSED PROJECT PERIODDIRECTCOSTSONLY |
| BUDGET CATEGORYTOTALS | INITIAL BUDGETPERIOD*(from Form Page 4)* | 2nd ADDITIONAL YEAR OF SUPPORT REQUESTED | 3rd ADDITIONAL YEAR OF SUPPORT REQUESTED | 4th ADDITIONAL YEAR OF SUPPORT REQUESTED | 5th ADDITIONAL YEAR OF SUPPORT REQUESTED |
| PERSONNEL: *Salary and fringe benefits. Applicant organization only*. |       |       |       |       |       |
| CONSULTANT COSTS |       |       |       |       |       |
| EQUIPMENT |       |       |       |       |       |
| SUPPLIES |       |       |       |       |       |
| TRAVEL |       |       |       |       |       |
| INPATIENT CARECOSTS |       |       |       |       |       |
| OUTPATIENT CARE COSTS |       |       |       |       |       |
| ALTERATIONS ANDRENOVATIONS |       |       |       |       |       |
| OTHER EXPENSES |       |       |       |       |       |
| DIRECT CONSORTIUM/CONTRACTUALCOSTS |       |       |       |       |       |
| SUBTOTAL DIRECT COSTS*(Sum = Item 8a, Face Page)* |       |       |       |       |       |
| F&A CONSORTIUM/CONTRACTUALCOSTS |       |       |       |       |       |
| TOTAL DIRECT COSTS |       |       |       |       |       |
| TOTAL DIRECT COSTS FOR ENTIRE PROPOSED PROJECT PERIOD | $ |       |
| JUSTIFICATION. Follow the budget justification instructions exactly. Use continuation pages as needed.      |

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# Letters of Recommendation

*Three letters of reference should be submitted from well-established scientists addressing the above areas and any other evidence that the candidate has a high potential for becoming an independent investigator in patient-oriented research. The mentor(s) may also submit letters of reference, but these are considered independent of the three required. All letters of reference should be submitted by the scientists directly through the REDCap portal. A custom link will be sent after their contact information has been entered in the Application portal.*

*Note: This page should* ***not*** *be included in the final application submission.*