|  |
| --- |
|   Trustee Award Application May 2024  ***Applications should be sent to Tony De Falco*** ***(Trustee Award Program Director) at*** ***Tony.DeFalco@cchmc.org*** |
| 1. TITLE OF PROJECT *(Do not exceed 81 characters, including spaces and punctuation.)*      |
| **2. PRINCIPAL INVESTIGATOR** |  |
| 2a. NAME *(Last, first, middle)*      | 2b. DEGREE(S) |  |
|       |       |       |  |
| 2c. POSITION TITLE      | 2d. TELEPHONE      |
| 2e. DIVISION      | 2f. E-MAIL ADDRESS      |
| 2g. DEPARTMENT/INSTITUTE       |  |
| 3. HUMAN SUBJECTS RESEARCH | 3a. Research Exempt  |  |
|  [ ]  No [ ]  Yes If yes approval date: | [ ]  No [ ]  Yes |       |
| 3b. Clinical Trial | 3c. NIH-defined Phase III Clinical Trial |
| [ ]  No [ ]  Yes | [ ]  No [ ]  Yes |
| 4. Vertebrate Animals [ ]  No [ ]  Yes4a. If “Yes,” IACUC Approval Date      4b. Animal Welfare Assurance No.       | 5. IBC Protocol [ ]  No [ ]  Yes5a. If “Yes,” Approval Date:      5b. Approval Number:       | 6. Radiation[ ]  No [ ]  Yes6a. If “Yes,” Approval Date      |
| 7. DATES OF PROPOSED PERIOD OF  SUPPORT *(month, day, year—MM/DD/YY)* | 8.COSTS REQUESTEDYear 1 ($)      |  |
| From | Through |  |  |
|  |  |
| 9. The undersigned reviewed this application for a CCHMC Trustee research grant award and are familiar with the policies, terms, and conditions of CCHMC concerning research support and accept the obligation to comply with all such policies, terms, and conditions. |
| Principal Investigator:      | Division Chief/ Dept Chair/Institute Director of Primary Applicant:      |
| Signature of Primary Applicant | Date: | Signature of Division Chief/Dept Chair/Institute of Primary Applicant | Date:       |

 Face Page **Form Page**

|  |  |
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| Program Director/Principal Investigator (Last, First, Middle): |       |
|  |
| PROJECT SUMMARY: Using technical language, briefly describe the research design and rationale for achieving the stated goals. |
|       |
| RELEVANCE: Using no more than two or three sentences, describe the relevance of this research to public health. |
|       |
| DIVISION, DEPARTMENT, OR INSTITUTE |
| KEY PERSONNEL. *Use continuation pages as needed* to provide the required information in the format shown below.Start with Principal Investigator. List all other key personnel in alphabetical order, last name first. |
| Name | Organization | Role on Project |
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 Page 2 **Form Page 2**

|  |  |
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| Principal Investigator/Program Director (Last, First, Middle): |       |
| Trustee Grant Application |
| TABLE OF CONTENTS |
|  | *Page Numbers* |
| 1. Face Page  |  | 1 |  |
| 2. Project Summary, Relevance, Division or Institute, Personnel  |  | 2 |  |
| 3. Table of Contents  |  | 3 |  |
| 4. Detailed Budget For Year 1 and 2  |  | 5 |  |
| 5. Budget Justification  |  | 6 |  |
| 6. Biographical Sketch – Principal Investigator and Co-Investigator (if applicable)  |  | 7 |  |
| 7. Other Support of Principal Investigator and Co-Investigator (if applicable)  |  |       |  |
| 8. Research Plan  |  |       |  |
| A. Introduction to Resubmission Application, if applicable  if applicable \*  |  |       |  |
| B. Specific Aims  |  |       |  |
| C. Research Strategy…………...……………………………………………B-C: not to exceed 5 pages\*  |  |       |  |
| D. Literature Cited  |  |       |  |
| E. Human Subjects (Protections, Safety Monitoring and Inclusions)  |  |       |  |
| F. Vertebrate Animals  |  |       |  |
| G. Resource Sharing Plan(s)  |  |       |  |
| H. Data Management and Sharing Plan(s)  |  |       |  |
| I. Authentication of Key Biological and/or Chemical Resources |  |       |  |
| J. Brief description of career development and Plan for R01 |  |       |  |
| K. Divisional Commitment from Division Chief |  |       |  |
| L. Mentoring Plan from Primary Scientific Mentor(s) |  |       |  |
| M. Letters of Support (e.g., Mentor and Collaborators or Consultants) |  |       |  |
|  |  |

\*For revised applications- not to exceed 6 pages by the inclusion of “Introduction / Response to Previous Review”

 Page 3 **Form Page 3**

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| DETAILED BUDGET FOR YEAR 1DIRECT COSTS ONLY | FROM | THROUGH |
|  |  |
| PERSONNEL *(Applicant organization only)* | Months Devoted to Project |  | DOLLAR AMOUNT REQUESTED *(omit cents)* |
| NAME | ROLE ONPROJECT | Cal.Mnths | Acad.Mnths | SummerMnths | INST.BASESALARY | SALARYREQUESTED | FRINGEBENEFITS | TOTAL |
|       | PrincipalInvestigator |       |       |       |       | 0 | 0 | 0 |
|       |       |       |       |       |       |       |       |       |
|       |       |       |       |       |       |       |       |       |
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| SUBTOTALS |       |       |       |
|  |
| CONSULTANT COSTS      |       |
| EQUIPMENT *(Itemize)*      |       |
| SUPPLIES *(Itemize by category)*      |       |
| TRAVEL      |       |
| PATIENT CARE COSTS | INPATIENT |       |       |
| OUTPATIENT |       |       |
| OTHER EXPENSES *(Itemize by category)*      |       |
| TOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD *(Item 9, Face Page)* | $ |       |

 Page 4 **Form Page 4**

|  |  |  |
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| DETAILED BUDGET FOR YEAR 2DIRECT COSTS ONLY | FROM | THROUGH |
|  |  |
| PERSONNEL *(Applicant organization only)* | Months Devoted to Project |  | DOLLAR AMOUNT REQUESTED *(omit cents)* |
| NAME | ROLE ONPROJECT | Cal.Mnths | Acad.Mnths | SummerMnths | INST.BASESALARY | SALARYREQUESTED | FRINGEBENEFITS | TOTAL |
|       | PrincipalInvestigator |       |       |       |       | 0 | 0 | 0 |
|       |       |       |       |       |       |       |       |       |
|       |       |       |       |       |       |       |       |       |
|       |       |       |       |       |       |       |       |       |
|       |       |       |       |       |       |       |       |       |
|       |       |       |       |       |       |       |       |       |
|       |       |       |       |       |       |       |       |       |
| SUBTOTALS |       |       |       |
|  |
| CONSULTANT COSTS      |       |
| EQUIPMENT *(Itemize)*      |       |
| SUPPLIES *(Itemize by category)*      |       |
| TRAVEL      |       |
| PATIENT CARE COSTS | INPATIENT |       |       |
| OUTPATIENT |       |       |
| OTHER EXPENSES *(Itemize by category)*      |       |
| TOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD *(Item 9, Face Page)* | $ |       |

 Page 5 **Form Page 4**

|  |  |
| --- | --- |
| Principal Investigator/Program Director (Last, First, Middle): |       |
|  |
| BUDGET JUSTIFICATION.       |

 Page 6 **Form Page 5**

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME:

eRA COMMONS USER NAME (credential, e.g., agency login):

POSITION TITLE:

EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)

| INSTITUTION AND LOCATION | DEGREE(if applicable) | Completion DateMM/YYYY | FIELD OF STUDY |
| --- | --- | --- | --- |
|  |  |  |  |
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**NOTE: The Biographical Sketch may not exceed five pages. See** [**NIH instructions**](https://grants.nih.gov/grants/forms/biosketch.htm) **for details and samples.**

**A. Personal Statement**

Briefly describe why your experience and qualifications make you particularly well-suited for your role (e.g., PD/PI, mentor, participating faculty) in the project that is the subject of the application.

**B. Positions, Scientific Appointments, and Honors**

List in chronological order previous positions, concluding with the present position. List any honors. Include present membership on any Federal Government public advisory committee.

**C. Contribution to Science**

Briefly describe up to five of your most significant contributions to science. For each contribution, indicate the historical background that frames the scientific problem; the central finding(s); the influence of the finding(s) on the progress of science for the application of those finding(s) to health or technology; and your specific role in the described work. For each of these contributions, reference up to four peer-reviewed publications or other non-publication research products (can include audio or video products; patents; data and research materials; databases’ educational aids or curricula’ instruments or equipment; models’ protocols; and software or netware) that are relevant to the described contribution. The description of each contribution should be no longer than one half page including figures and citations. Also provide a URL to a full list of your published work as found in a publically available digital database such as SciENcv or My Bibliography, which are maintained by the US National Library of Medicine.

**For New and Renewal Applications – DO NOT SUBMIT UNLESS REQUESTED**

**PHS 398 OTHER SUPPORT**

*There is no "form page" for reporting Other Support. Information on Other Support should be provided in the format shown below.*

\*Name of Individual:

Commons ID:

**Other Support – Project/Proposal**

\*Title:

Major Goals:

\*Status of Support:

Project Number:

Name of PD/PI:

\*Source of Support:

\*Primary Place of Performance:

Project/Proposal Start and End Date: (MM/YYYY) (if available):

\* Total Award Amount (including Indirect Costs):

\* Person Months (Calendar/Academic/Summer) per budget period.

| Year (YYYY) | Person Months (##.##) |
| --- | --- |
| 1. [enter year 1]  |  |
| 2. [enter year 2]  |  |
| 3. [enter year 3] |  |
| 4. [enter year 4] |  |
| 5. [enter year 5] |  |

**IN-KIND**

\*Summary of In-Kind Contribution:

\*Status of Support:

\*Primary Place of Performance:

Project/Proposal Start and End Date (MM/YYYY) (if available):

\*Person Months (Calendar/Academic/Summer) per budget period

|  |  |
| --- | --- |
| Year (YYYY) | Person Months (##.##) |
| 1. [enter year 1]  |  |
| 2. [enter year 2]  |  |
| 3. [enter year 3] |  |
| 4. [enter year 4] |  |
| 5. [enter year 5] |  |

\*Estimated Dollar Value of In-Kind Information:

**\*Overlap** (summarized for each individual):

I, PD/PI or other senior/key personnel, certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

\*Signature: ­­­­­­­­­­­­­­­­­­­­­­­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: ­­­­­­­­­­­­­­­­­­­­­­­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Research Plan**: 5 pages (6 pages for resubmission)

* 1. Introduction to Resubmission describing response to previous review (**1 additional page if applicable**).
	2. **Specific Aims (1/2 page):** Remember this is a 1-2 year pilot project.
	3. **Research Strategy (4 ½ pages).** Organize the Research Strategy into three sections - *Significance*, *Innovation* and *Approach* using the instructions provided below. Include a thorough, but concise description of the work leading up to your current hypothesis. The research strategy should be written using language that can be evaluated by non-expert reviewers (i.e., accessible to NIH-level reviewers outside the field).
		+ **Significance**: Describe the scientific premise for the proposed project and explain how the work will address an important problem or a critical barrier in the field. Explain how this proposal will generate the preliminary data needed for an NIH R01 grant application.
		+ **Innovation**: Explain how the proposal challenges existing paradigms or clinical practice; address an innovative hypothesis or critical challenge in the field.
		+ **Approach**: Describe the overall strategy and analyses used to accomplish the specific aims of the project. Include preliminary data, a rationale for experimental design and discuss any potential problems and solutions. In keeping with new NIH guidelines, describe methods to ensure robustness and reproducibility and explain how relevant biological variables (i.e., sex) are factored into the research design. [See NIH guidance regarding rigor and reproducibility](https://grants.nih.gov/policy/reproducibility/index.htm).
	4. Literature cited. Provide full details of literature cited including full title and authors.
	5. Human Subjects. Include all required sections required for NIH application.

 [See NIH instructions for more information](https://humansubjects.nih.gov/nih-human-subjects-policies-guidance).

* 1. Vertebrate Animals. Include 4-point narrative required for NIH application.

 [See NIH instructions for more information](https://olaw.nih.gov/guidance/vertebrate-animal-section.htm).

* 1. Resource Sharing Plan. [See NIH instructions for more information](https://grants.nih.gov/policy/sharing.htm).
	2. Data Management and Sharing (DMS) Plan.

[See NIH instructions for more information](https://sharing.nih.gov/data-management-and-sharing-policy).

* 1. Authentication of Key Biological and/or Chemical Resources.

 [See NIH instructions for more information](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-068.html).

* 1. Brief description of how the proposal supports your career development and your subsequent NIH R01 application **(1 page).**
* Brief synopsis of your career and long-term goals
* Describe your plan for an NIH R01 grant application and how the Trustee Award will help you achieve this.

K-L. Statement of Divisional commitment by the Division Chief **and** mentoring plan by the applicant’s primary scientific mentor(s) **(1 page each).**

* Describe the mentoring plan and career development support of the applicant.
* Describe Divisional support currently available to the applicant – start up package, research space and any other resources relevant to the application.
* Please include the Division Chief and Scientific Mentor’s name in the statements.
1. Letters of support from collaborators, consultants or mentoring committee.