**ORPHAN DISEASE CENTER and LOULOU FOUNDATION**

**CDKL5 Program of Excellence**

**PILOT GRANT PROGRAM**

**Full Application**

**Cover Page**

PI Name:

PI Title:

PI Institution:

Project Title:

Human Subjects Research:  Yes (Please attach IRB approval letter)  No

Animal Research:  Yes (Please attach IACUC approval letter)  No

Abstract (Up to 250 words):

**Checklist**

**ATTACH:**

**Cover Page/Checklist/Institutional Signature Page [PDF]**

**NIH-style Biosketch with Other Support of PI and key personnel** (5 pages maximum for each PI) **[PDF]**

The PI must include accurate and complete information regarding all other sources of grant support (current and pending), including title, abstract, annual and total amount of grant, inclusive funding period, and percent effort.

**Detailed Budget and Justification** **[combined into one PDF]**

Complete attached Excel budget sheet. Describe justifications in a Word document. Award will be for one year. Proposed funding period: May 1, 2022 – April 30, 2023.

|  |  |
| --- | --- |
| **Allowable direct costs** | **Unallowable costs** |
| * Salary for PI * Salary/stipend and related benefits for graduate student/postdoctoral fellow/technical support * Travel (up to $1500) * Laboratory supplies and other research expenses | * Salary/consultant costs * Tuition * Professional membership dues * Equipment >$5,000 * General office supplies, institutional administrative charges (e.g., telephone, other electronic communication, IT network, etc.) * Pre‐award charges * Any other expenses not directly related to the project |

**Research Plan** (5 pages max) and **Bibliography** (1 page max) **[combined into one PDF]**

Include the following sections: Lay Summary (to be shared publicly if grant is awarded), Specific Aims, Background and Significance, Preliminary Studies/Data, Research Design and Methods.

Text citations should use a numbered format. Include all author names in the reference list.

**Appendix** **[combined into one PDF]**

Limited to 5 pages of supplemental information pertaining to proposal or preliminary data only; a maximum of 3 relevant reprints are also acceptable. Include IRB and/or IACUC approval letters if relevant.

**ORPHAN DISEASE CENTER**

**CDKL5 PROGRAM OF EXCELLENCE PILOT GRANT PROGRAM**

**INSTITUTIONAL SIGNATURE PAGE**

**Certification and Acceptance:**

We, the undersigned, certify that the statements contained in the attached grant application are true and complete to the best of our knowledge. We agree to conform to the policies and rules governing this award. We agree to openly share final data sets and observations with the full scientific community, and all reagents and/or research tools developed under support by this mechanism will be made accessible upon request. We understand that the University of Pennsylvania makes no claim to rights on these items or intellectual property other than for those faculty employed by the University of Pennsylvania. We understand that indirect costs are limited to a maximum of 10% of direct costs.

**Principal Investigator:**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Name (typed) Signature

Title:

Institution:

Department:

Address:

Phone:Fax:

E-mail:

**Institutional Official:**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Name (typed) Signature

Title:

Institution:

Department:

Address:

Phone:Fax:

E-mail:

**ORPHAN DISEASE CENTER**

**CDKL5 PROGRAM OF EXCELLENCE**

**PILOT GRANT PROGRAM**

**Grant Program Award Terms**

The following terms and conditions will apply to the awarded grantee/institution and subcontract institutions.

This award is based on the application for the above-referenced project submitted to, and as approved by the University of Pennsylvania and is subject to the terms and conditions below.

The Award is contingent upon the availability of funds and is subject to the Terms and Conditions herein, which may be revised from time to time. By accepting an Award, the Principal Investigator and the Grantee Institution agree to be bound by the Terms and Conditions.

Funding for this Award is provided by the generous contribution of the Loulou Foundation (the “LLF”). LLF and ODC have partnered in establishing a Program of Excellence (the “POE”) in CDLK5 research within ODC with the goal of developing effective treatments for patients with a deficiency of CDKL5.

**PAYMENT**

Funds will be issued through cost reimbursement mechanism executed by purchase order from the University of Pennsylvania. We have been advised by our Office of Research Services that due to the nature of this award, unless your institution objects, we will be able to forego the institutional signatory process (subaward agreement) and proceed directly with creating a purchase order for quarterly invoicing of award. Any changes to this schedule will be confirmed with the Grantee Institution upon a prior written notice.

**TERMS AND CONDITIONS**

1. Funds for this Award are provided by private philanthropy by LLF and administered by the University of Pennsylvania. All funds shall be used exclusively for the purposes provided for in the Award Application and in strict compliance with the approved Budget.
2. The total award amount is $150,000 (including direct and indirect costs). It is strongly preferred that applicant institutions waive indirect costs thereby allowing the total amount to go towards research, but indirect costs up to a maximum of 10% could be accepted in exceptional cases.

1. Travel <$1,500 is allowed, including international travel, as long as it is related to the Research Project.
2. Equipment >$5,000 is not allowed. Equipment qualifying as a capital asset is defined as an item with an acquisition cost of $5,000 or more. The acquisition cost of equipment includes installation charges and freight. Capitalized equipment can be identified as having all of the following characteristics:

a) Acquisition cost equal to or greater than $5,000;

b) Life span in excess of one (1) year;

c) Contains or is made of non-expendable material; and

d) Is not made for consumption

1. Reallocations between budget categories (Personnel, Supplies, Other Expenses) of 10% or less are allowable. Budget revisions in excess of 10% between categories require justification and prior approval by the University of Pennsylvania.
2. Oversight for use of animals and/or humans is the responsibility of the Grantee Institution. The Grantee Institution and Principal Investigator agree that animal and/or human use will comply with all applicable laws and regulations, including but not limited to current EPA, FDA, USDA, and NIH guidelines. Please note: no work on animals or humans may proceed until current IACUC or IRB approvals are received by the University of Pennsylvania.
3. Appropriate citation of all collaborations must be included in all publications resulting from the Award.
4. All final data sets and observations must be shared openly with the full scientific community, and all reagents and/or research tools developed under this Award must be made accessible upon request.
5. Policies for managing intellectual property resulting from research utilizing the Award and sharing of potential licensing revenue are determined by the LLF. Prior to release of funding for approved Awards, the University of Pennsylvania must receive signed confirmation that the Grantee Institution and the LLF have agreed to the management of intellectual property resulting from research utilizing the Award and sharing of potential licensing revenue, in the form attached hereto as Exhibit C. Any disputes regarding such intellectual property/licensing revenue sharing must be adjudicated between the LLF and the Grantee Institution. The terms of the LLF Patent Policy shall survive termination of the Award Terms and Conditions.
6. The University of Pennsylvania reserves the right to share the full application, as well as progress reports and the final report with the LLF, which they will be receiving under confidentiality. LOIs and full applications will also be shared with external reviewers, after they sign a confidentiality agreement. The University of Pennsylvania reserves the right to share the following information about the Award with the public: Principal Investigator name, Award amount, title of Award/Research Project, and a non-confidential, lay-language final report and project summary (provided during the application process).
7. The Principal Investigator of the award will be expected to attend an annual meeting for the CDKL5 POE (Forum). LLF will reimburse such representative directly for reasonable, pre-approved travel expenses related to this meeting.

For additional information, please contact Alexis Zavez at [azavez@upenn.edu](mailto:azavez@upenn.edu)   
or 267-648-1730.

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