PEDIATRIC EPILEPSY RESEARCH FOUNDATION®
APPLICATION SUBMISSION GUIDELINES

The PERF® Grant for Infrastructure/Registry Research is up to 3 years of support for up to $300,000.00. Grants are for $100,000 per year for each of three years with $10,000 withheld from Year 1 payment. The Grant Application should include a description of the project, a total estimated cost, and benefits to be derived. Any supporting documents, e.g., research plan should be included. Please see "**Application Submission Instructions**" for exact instructions on page 4.

When the application is received, it will be reviewed for thoroughness and receipt will be acknowledged.

~ No indirect costs are provided. ~

1.   It is appropriate for investigators to share these instructions with ALL personnel assisting you with your grant application (including the grants office regarding the intellectual property policy).

2.   A letter of exemption from the Internal Revenue Service (with the tax identification number of the primary study site) needs to be included.

3.   Proposals from faculty less than 10 years post-training or those exploring new research tracks are requested to provide a Mentoring Plan.in Core Section 8.

4.   At least one child neurologist must be a member of the core study team as a PI, co-PI, or co-investigator.

5.   Grant funding is contingent upon IRB/IACUC approval of your project (if applicable). Notice of current IRB/IACUC approval must be received by sponsor prior to receiving financial payment.

6.   Proposed Statistical Analysis and Sample Size Calculation. Provide clear justification for the sample size proposed and the statistical analysis plan for the proposed aims. As part of the statistical analysis there should be prespecified primary outcomes and primary analysis and secondary outcomes and secondary analysis (if any). Also, include some discussion on how missing data will be handled, especially if the application involves a randomized trial.

7.   Two letters of recommendation but no more than 4, are required. At least one reference letter must include a ==yellow highlighted statement== that documents the willingness of the institution to accept the grant without indirect costs and provision of sufficient protected time to perform the research described in the application. PERF® grant funds must be applied above and beyond any research support already provided by the investigator's institution. PERF salary support cannot offset salary or expenses the institution already covers. These highlighted statements are to be included in a letter from the applicant's Section Chief or Department Chair. This letter is mandatory.

8.   Once a grantee is selected for a grant, they shall execute the Foundation "Grant Agreement" as a condition of grant acceptance. A protocol will need to be provided. CRFs, MOP, DSMB, etc. should be included if appropriate. A report on the use of funds and effectiveness of the project (progress report) must be submitted to the Foundation the year following the grant and all subsequent year(s). Ten percent (10%) of the grant will be withheld each year pending receipt of your report. A final report and financial accounting must be submitted at the conclusion of the project.

9.   All applicants will be notified of the board's decision by the 30th of June of the submitting year.

10.   The grantee's institution should be prepared to cash the grant check within one month of receipt of the payment.

11.   At PERF®, we understand that generative AI can be used by some investigators as they write proposals. Our expectation is that your application reflects your own work.

PEDIATRIC EPILEPSY RESEARCH FOUNDATION® APPLICATION SUBMISSION GUIDELINES

IMPORTANT INFORMATION:
Applications are due no later than 5:00 pm (central time zone), Friday, April 18, 2025. There are no extensions.

It is suggested you provide the application packet and forms to all staff assisting you with completion of this grant application. If you are working jointly with co-investigator(s), one site will need to be designated as the primary site where PERF funds will be sent should your proposal be funded.

Merge all documents into one PDF, in the specific order listed below. A Table of Content is REQUIRED after the signed face page:

CORE SECTION

Core Section	Document	Limit: Page, Line, or Word
1	Face Page	Two pages
2	Table of Content	Two pages
3	List of Abbreviations	None
4	Abstract	Not to exceed 300 words
5	Lay Summary	Not to exceed 300 words
6	Specific Aims	One page
7	Research Proposal	Twelve-pages
8	Mentoring Plan	Two-pages
9	Multiple PI Leadership Plan	One page
10	Biographical Sketches	Five pages per person
11	Other Support Page	None
12	Budget	One page
13	Budget justification	No limit
14	Resources	One page per site including submitting site.
15	Letters of Recommendation	Two-pages each
16	References Cited	None

APPENDIX
Appendix Items, as applicable. An asterisk* indicates a required document if a project requires IRB or IACUC. Note: it is understandable the following items may not be available at time of submission; however, they will be required to be submitted to the sponsor at time of award announcement and are required before the proposal is funded.

Appendix	Document
1	Performance Sites and Key Personnel, which should align with submitted biosketches. (one page limit)
2	Awardee Financial Information (one page limit)
3	501(c)3 (non-profit) proof of status.
4*	Human Subjects
5*	Vertebrate Animals
6*	IRB Approval Letter
7*	IACUC Approval Letter
8*	Research Protocol (12-page limit)
9*	Case Report Forms (CRF)
10*	Manual of Operations (MOP)
11*	Data Safety Monitoring Board (DSMB) Plan
12	PERF® Terms and Conditions of Award

FORMATTING REQUIREMENTS

- Single Spaced
- Standard paper size (8.5 x 11)
- ½" Margins
- 11-point Arial font
- Font color should be black
- Use only a standard, single-column format for the text. A two-column format can create difficulties when reviewing the document electronically.
- If the research plan includes figures, graphs, diagrams, tables, figure legends and/or footnotes, a smaller type size is allowable, but it must be a black font color, readily legible, and follow the font typeface requirement. Color can be used in figures.

GRANT APPLICATION CHECKLIST

☐   Assurance the application reflects the PI's work.

☐   All core application section forms

☐   Appendix Items, as applicable

☐   Letter from Division Chief or Department Chair

☐   Additional Reference Letter(s)

Convert the entire proposal and appendix to a PDF format and submit online to Karen McEwen, Executive Director, PERF® at perf2004@gmail.com and copy Jo Anne Nakagawa at nakaj.perf@gmail.com
The complete proposal must be received by 5:00 pm (Central Time Zone) April 18, 2025.

Applications that do not adhere to the sanctioned procedures will be returned without review. The applicant will be informed of the Committee's decision by June 30, 2025.

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APPLICATION SUBMISSION INSTRUCTIONS**

APPLICATION SUBMISSION INSTRUCTIONS | CORE SECTION

Application Face Page: (one page limit)
Complete application page and obtain institutional signature.

List of Abbreviations:
Provide a list of all abbreviations used in application. Please limit unnecessary use of non-standard abbreviations.

Abstract: (not to exceed 300 words)
The abstract should provide information about the significance, broad objectives, hypotheses, specific aims and anticipated methods to be used. A statement should be included of how the project relates to the mission of PERF™. Do not include graphs or images.

Lay Summary: (not to exceed 300 words)
Provide a summary describing the proposed work, using short sentences and simple sentence constructions. This means use everyday language. Omit technical, medical terminology and acronyms. The summary must be understandable by non-medical members of the PERF® Board of Directors and staff. Do not include proprietary/confidential information. This summary should describe how this project will develop a new or enhance an existing infrastructure/registry in a pediatric neurologic disorder. Resource: Consider using the Flesch-Kincaid Readability Calculator (https://goodcalculators.com/flesch-kincaid-calculator/) to test the general readability of your summary.

Specific Aims: (one page limit)
Begin with a brief narrative that clearly indicates the concern or problem to be addressed in the proposal. State the long-term goals or objectives of the proposal and clearly state the hypothesis to be tested. List 2-4 specific aims; aims should be logical, achievable and clearly relate back to the research or hypothesis. The final paragraph/sentence should be an impact statement stating what will become possible that currently isn't, how the research/project will impact the scientific field.

Research Proposal**: (twelve-page limit) Suggest NIH layout and information, starting on page 168:
https://grants.nih.gov/grants/how-to-apply-application-guide/forms-h/general-forms-h.pdf
       Significance
       Innovation
       Approach
**Please use terms/phraseology that a general neurologist would understand.

Mentorship Plan: (two-page limit)
The primary goal of this grant mechanism is to establish and/or expand the scientific scope of multicenter clinical research collaborations to (1) support meaningful clinical research to improve the lives of children with neurologic disease, and (2) prepare the investigators to develop competitive subsequent research grant applications (e.g. to NIH, PCORI, CIHR etc.). Mentorship is a key value for PERF®. Therefore, every application must provide a mentoring plan (maximum 2 pages).
Early-Stage Investigators (faculty less than 10 years post-training who have not held major independent grants – e.g. NIH R01, CIHR Project Grant or equivalent – or those beginning new lines of research topics or methods) who serve as principal investigators (PIs) on PERF® grants must demonstrate that their mentorship plan provides the necessary support for them to execute the proposed study.
(1)   PERF® grants are not traditional career development awards. They are intended to develop multicenter research networks. Thus, the mentorship plans for these grants should be specific to the proposal.

APPLICATION SUBMISSION INSTRUCTIONS | CORE SECTION, continued

(2) This plan should clearly indicate how the PI will be supported as an early-stage investigator to be successful in leading this multicenter study. The plan should include a detailed strategy for professional activities/responsibilities and specific mentorship that will enable the PI to successfully lead the proposed research project and foster the PI's development as an independent pediatric neurology researcher.

(3) Ideally, the primary mentor shall be local (i.e., at the same institution as the PI). However, in some circumstances the most appropriate primary mentor may be at another institution/organization. In this case, provide a clear description of how the PI will work with the primary mentor and how the PI will receive local mentorship on navigating the internal systems at their home institution.

(4) Research mentors must have a track record in (1) pediatric neurology research or another area that is relevant to the application, and (2) multicenter study leadership. It is acceptable to have multiple mentors for different aspects of the study. The mentors' involvement in the proposal design and planned execution should be clearly described.

(5) For each mentor, provide evidence of a track record of mentoring productive early-stage investigators, as evidenced by the mentor's career evolution, productivity, extramural funding, publication record, and the productivity of their prior mentees.

(6) In the mentorship plan, indicate how often the PI will meet with their mentor(s), how these meetings will be conducted (in person, Zoom, etc.), etc. If there is a mentorship team, outline how this team will work together to support the PIs successful leadership of the multicenter project.

Established Investigators may also serve as PIs for PERF® Infrastructure and Registry Grants. These PIs must demonstrate the appropriate skills to lead the multicenter study. They shall explain in their mentorship plan how they will mentor early career investigators involved in the study (e.g., assistant professors, instructors, fellows, or people who are new to clinical research).

(1) Provide evidence of a track record of mentoring productive early-stage investigators, fellows and other trainees. Include information about experience in providing the proposed research mentorship, as evidenced by the PI's career evolution, productivity, extramural funding, publication record, and the productivity of prior mentees.

(2) Provide a comprehensive mentoring plan which details how the PI will facilitate the research career development of more junior investigators who participate in this multicenter research. Include information about potential impact of the proposed mentoring plan. Describe plans for virtual communication strategies, teleconferences, networking, training, etc., along with how frequently these activities will occur and how their outcomes will be assessed.

Multiple PI (MPI) Leadership Plan (2-page limit)

- <u>Rationale</u>: Briefly describe the reason the project requires multiple PIs. Designate who will serve in a leadership role and include a brief description of their leadership experience. Example: Dr. Jones and Dr. Smith have held bi-weekly research meetings for 5 years to develop and execute joint projects.
- <u>Study Oversight</u>: Describe who will provide joint oversight of the entire project and specify what they will do as PI. Who will oversee budgetary matters, regulatory and data management, etc.?
- <u>Communication Plan</u>: Describe who will share responsibility for communications with study sites about study progress reports, for example, and what methods will be used to communicate.
- <u>Process for Conflict Resolution</u>: Describe your plan for resolving a conflict should one occur about the scientific plan.
- <u>Change in PI Leadership</u>: Briefly describe your plan if one or more PI moves to another institution.
- <u>Publications</u>: Describe your authorship policy.
- <u>Summary</u>: Summarize in lay language your overall leadership plan.

APPLICATION SUBMISSION INSTRUCTIONS | CORE SECTION, continued

Biographical sketch: (five-page limit)
Key personnel and primary mentor^.   Key personnel are individuals who contribute in a significant, meaningful way to the scientific development or execution of the project. This typically does not include technicians or others unless they provide specific expertise or have a skillset needed to complete the proposed research. Use the standard NIH Bio sketch template https://grants.nih.gov/grants/forms/biosketch.htm.

^Inclusion of a mentor also applies to a senior investigator who is changing their scope of research

Budget: (use provided excel spreadsheet) NO INDIRECTS PROVIDED
Enter costs for each requested budget period. The budget period is 12 months (September 1-August 31). Expenses only related to this project should be requested. Any individual (PI, Co-PI, mentor, support staff, etc.) contributing to the research project can receive salary support appropriate for work outlined in the proposed budget.   PERF® utilizes the NIH Salary Cap for the infrastructure/registry awards. For the current salary cap go to https://grants.nih.gov/policy-and-compliance/policy-topics/nih-fiscal-policies/salary-cap-summary

Budget Justification: (no page limit)
Provide a justification for the budget requested under each category provided on the Excel spreadsheet. If no budget is requested for a category, indicate "not applicable".

Resources: (one page limit per site)
List resources/facilities and available major equipment that are relevant to the proposed research and are required to undertake and complete the proposed research successfully.

Other Support: (no page limit)
Use the standard NIH Other Support template https://grants.nih.gov/grants/forms/all-forms-and-formats/other-support-format. Applicants should provide funding information on active and pending support. Other support is to include all resources made available to the applicant. Other support is necessary to verify there is no budgetary or scientific overlap or commitment of effort greater than 12 person-months for the PI, or if applicable their mentor.

References Cited Additional Information: (no page limit)
The references cited in the research plan, or any other parts of the application must follow the style standards established by the National Library of Medicine (NLM):

List all authors, last name first, then first initial, and middle initial, if available, separate each author by a comma. List full article title, capitalize only first word and any proper nouns. Abbreviate journal title according to NLM Catalog of Journals[1]. Put year first, followed by month and date, if listed.

References are to be uploaded as a separate file and are not included in the research plan page limit.

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[1] https://www.ncbi.nlm.nih.gov/nlmcatalog

Performance Sites and Key Personnel: (one page limit)
Complete required information on form.

Awardee Financial Information: (one page limit)
Complete required information on form.

501(c)3 proof of status:
Provide a letter of exemption from the Internal Revenue Service (with the tax identification number of the primary study site).

Human Subjects: (no page limit)
Mark the "Not Applicable" box if the applicant is not using human subjects. Indicate the assurance status (active, pending, not submitted), the approval date and expiration date if known.
Succinctly state the characteristics of the subjects; research material source(s); plans for recruitment and obtaining consent procedures; any potential risks to subject; processes for protecting against or minimizing potential risks.
Inclusion of Women and Minorities: Discuss the demographics of the minority populations in the area and the criteria and rationale for selection of gender and racial/ethnic group, as well as your plan for recruiting/ including women and minorities in the research.
Targeted Enrollment Table: estimate participation in the study by gender and ethnicity.
Inclusion of Children: Discuss the participation of children and explain the rationale if children are excluded. If they are included, describe the rationale for selecting demographics: age, sex, etc.

Vertebrate Animals: (no page limit)
Mark the "Not Applicable" box if the applicant is not using animal subjects. Indicate the assurance status (active, pending, not submitted), the approval date and expiration date if known.
Give a detailed description of the proposed use of the animals in the work outlined in the Research Strategy section. State the species, strains, ages, sex, and numbers of animals to be used in the proposed work. Provide information on the veterinary care of the animals involved. Describe the procedures for ensuring that discomfort, distress, pain, and injury will be limited to that which is unavoidable in the conduct of scientifically sound research. Describe the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices, where appropriate, to minimize discomfort, distress, pain, and injury. Describe any method of euthanasia to be used and the reasons for its selection. Indicate whether this method is consistent with the recommendations of the American Veterinary Medical Association (AVMA) Guidelines on Euthanasia. If not, include a scientific justification for not following the recommendations.

IRB Approval Letter: (no page limit)
May be provided at time of funding if institutional approval has not been received.

IACUC Approval Letter: (no page limit)
May be provided at time of funding if institutional approval has not been received.

Protocol: (no page limit)
May be provided at time of funding if institutional approval has not been received.

Case Report Forms: (no page limit)
May be provided at time of funding if institutional approval has not been received.

Manual of Operations: (no page limit)
May be provided at time of funding if institutional approval has not been received.

Data Sharing/Safety Monitoring Plan: (no page limit)
Define the data generated by your research and how it will be FAIR (**f**indable, **a**ccessible, **i**nteroperable, **r**eusable), and what your plan is for dissemination and sharing. Data is any information generated through this research, including clinical data, sequencing data, etc. State data standards that will be used, and if none are available, how this will be addressed.

PERF® Terms and Conditions of Award for Potential Grantee
Include signed form with your application.   If your proposal is selected for funding, this form and the Intellectual Property Policy will require institutional signature as part of the Grant Agreement.

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