

# Stanford Child Health Research Institute

Mobilize Stanford discoveries and expertise to launch healthier lives

## Clinician Educator Grants Program Application Instructions

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## **1. General Instructions**

### **1.1. Introduction**

These instructions pertain to applications for the Stanford Child Health Research Institute (SCHRI) Clinician Educator Grants Program sponsored by the Stanford Child Health Research Institute. For detailed program policy please refer to the Stanford CHRI Clinician Educator Grants Program Policy available at <http://spectrumchildhealth.stanford.edu/>.

### **1.2. Format Specifications**

Font and margin specifications must be followed; if not, application processing may be delayed or the application may not be reviewed. Page limits must be followed or the application may not be reviewed.

#### **Font**

- Use only *Arial, a black font color, and a font size of 10 points or larger*. A symbol font may be used to insert Greek letters or special characters; the font size requirement still applies.
- Type density, including characters and spaces, must be no more than 15 characters per inch.
- Type may be no more than six lines per inch.

#### **Page Margins**

- Use at least one-half (0.5) inch margins (top, bottom, left, and right) for all pages. No information should appear in the margins, including the PI's name and page numbers.

#### **Page Formatting**

- Use only a standard, single-column format for the text.
- Put applicant's last name in the footer on every page (except the face page)
- Consecutively number pages throughout the application. Do not use suffixes (e.g., 5a, 5b).
- Do not include unnumbered pages. Number all pages.

#### **Grantsmanship**

- Use English and avoid jargon.
- If terms are not universally known, spell out the term the first time it is used and note the appropriate abbreviation in parentheses. The abbreviation may be used thereafter. This section should be informative to others, such that a medical faculty member who is not a specialist in your field, will understand.

#### **Photographs and Images**

- Do not include photographs or other materials that are not printed directly on an application page in the body of the application.
- You may include black-and-white or color images in the application provided such images are printed directly on the application page and are critical to the content of the application.

## Figures, Graphs, Diagrams, Charts, Tables, Figure Legends, and Footnotes

- A smaller type size here is acceptable, but it must be in black ink, readily legible, and follow the font typeface requirement.

## Page Limits

Observe the page number limits provided in the table below.

SECTION OF APPLICATION	PAGE LIMITS
<b>Face Page</b>	1 page
<b>Budget and Budget Justification</b>	2 pages
<b>Introduction (Resubmission only)</b>	2 pages
<b>Research Plan</b>	4 pages
<b>Appendix ** (figures and references)</b>	3 pages

\*\* Applicants are prohibited from using the appendix to circumvent page limits in any section of the application for which a page limit applies.

## 1.3. Resubmission Applications

### Opportunity for Resubmission

For all applications originally submitted (i.e. for the first time) in 2007 or later (e.g., Innovations in Patient Care), Stanford CHRI will accept a maximum of two resubmissions per project (amendments to the original application). Any third resubmission will be administratively withdrawn and not accepted for review.

There are 3 requirements for a Resubmission application:

- The Applicant must make significant changes to the application;
- An Introduction (max 2 pages) must be included that summarizes the substantial additions, deletions and changes to the application. The Introduction must also include a response to the issues and criticism raised in the Reviewer Comments. Use the Introduction to Application of the Research Plan to provide this information. All format requirements apply.
- The substantial scientific changes must be marked in the text of the application by bracketing, indenting, or changing typography. If the changes are so extensive that essentially all of the text would be marked, explain this in the Introduction. The Research Plan should incorporate work completed since the prior version of the application was submitted.
- Research Plan should incorporate work completed since the prior version of the application was submitted.

Investigators who have submitted multiple versions of an application and have not been successful often ask what constitutes a “new application.” It is recognized that investigators are trained in a particular field of science and are not likely to make drastic changes in their research interests. However, a new application following multiple reviews is expected to be substantially different in content and scope with more significant differences than are normally encountered in a Resubmission application.

Simply rewording the title and Specific Aims or incorporating minor changes in response to the Reviewer Comments does not constitute a substantial change in scope or content. Changes to the Research Plan should produce a significant change in direction and approach for the research project. Thus, a new

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application would include substantial changes in all sections of the Research Plan, particularly the Specific Aims.

Applicants are encouraged to meet with a Stanford CHRI reviewer to discuss revisions and suggestions for improvement prior to resubmission. Contact Spectrum Child Health ([spectrumchildhealth@stanford.edu](mailto:spectrumchildhealth@stanford.edu)) to request a resubmission consultation with a reviewer.

### 1.4. Application Submission Date, Late Applications

The electronic (PDF) application **must** be received by Spectrum Child Health Administration via the following link, [https://stanfordmedicine.qualtrics.com/SE/?SID=SV\\_dgwLPnYbbFcETNb](https://stanfordmedicine.qualtrics.com/SE/?SID=SV_dgwLPnYbbFcETNb), **no later than 5pm on the submission deadline specified in the RFA.**

Submit your proposals to the link above, per the application instructions.

Please note that the budget, budget justification and/or proposal application should not be submitted to your RPM as these applications will be reviewed and processed by Spectrum Child Health. If you need assistance with your budget, please contact your business manager, financial analyst, or department accountant.

**Late applications.** Permission is **not** granted in advance for submission of a late application. Late applications are accepted only in extenuating circumstances. If an application is submitted late, a signed cover letter explaining the reasons for the delay **must** be included with the completed application. Late applications are evaluated on an individual basis considering the reasons provided. Contacting Spectrum Child Health Administration in advance will not influence the acceptance of a late application.

### 1.5. Post-Submission of Application Materials

Grant application materials will only be accepted after submission of the application but before the initial peer review if they result from *unforeseen administrative issues* (e.g., see below). A complete application with new materials should be emailed as a PDF attachment to [spectrumchildhealth@stanford.edu](mailto:spectrumchildhealth@stanford.edu).

The original application is kept intact; updated or supplemental grant application materials used in the peer review process will be retained as part of the official grant file and remain part of the permanent record for that application.

#### Acceptable post-submission materials include:

- Revised budget (e.g., change in total budget request due to new funding)
- Biographical sketches (e.g., change in senior/key personnel due to the loss of an investigator) or CV (if applicable)
- Letters of support or collaboration resulting from a change in senior/key personnel due to the loss of an investigator
- Adjustments resulting from natural disasters (e.g., loss of an animal colony)
- News of an article accepted for publication

#### Unacceptable post-submission materials include:

- Updated Specific Aims or Research Plan pages
- Late-breaking research findings
- Supplemental pages - information not contained in the existing application

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- New letters of support or collaboration that do not result from a change in senior/key personnel due to the loss of an investigator

### Page limits for post-submission materials:

- All post-submission materials must conform to the Stanford CHRI Clinician Educator Grants Program Application Instructions on font size, margins, and paper size
- Additional pages such as budget, biographical sketches, and other required forms must follow Stanford CHRI page limit requirements

The deadline for receipt of additional materials is one month (30 calendar days) prior to the peer review meeting. Contact Spectrum Child Health Administration if you may submit post-submission materials. After the initial peer review phase is completed, additional materials will not be accepted. However, if additional information is requested after a peer review of a grant application has been completed and prior to funding, the applicant will be notified by email.

## 1.6. Submission, Review and Award Cycles

### Timeline

Anticipate total review turnaround time of 12 weeks from the submission deadline.

### Application Assignment Information

Competing grant applications submitted to Stanford CHRI will be processed through Spectrum Child Health. The application will be assigned to an appropriate CHRI Scientific Review Panel. Assignment is based on the scientific content of the application and conflicts of interest considerations.

Applicants must **not** communicate directly with any Stanford CHRI Scientific Review Panel member about an application either before or after the review. Failure to strictly observe this policy will create serious breaches of confidentiality in the peer review process. From the time of assignment to the time the review of the application is complete, applicant must direct all questions to Spectrum Child Health Administration.

## 1.7. Resources for Finding Help

If, after reviewing these application instructions, help is needed in preparing the application, contact Spectrum Child Health Administration at [spectrumchildhealth@stanford.edu](mailto:spectrumchildhealth@stanford.edu) or calling 650-724-6891.

## 2. Submission of the Grant Application

**Submit a complete application.** The application must be complete and accurate at the time of submission. Applications may not be reviewed if they are incomplete, illegible, fail to follow instructions, or present insufficient material to permit an adequate review.

### 2.1. Bindings and Packaging

Submit the following materials into *one* PDF document. Collate application materials in this order:

- Face Page (maximum 1 page)
- Budget Worksheet and Budget Justification (maximum 2 pages)

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- Introduction (Resubmissions Only, maximum 2 pages)
- Research Plan (maximum 4 pages)
- Appendix (Figures and References; maximum 3 pages)
- Supporting Documents
  - NIH Biosketches (maximum 5 pages)
    - Applicant (Biosketch or CV accepted)
    - Mentor(s) – if any
    - Co-Investigator(s) – if any
  - Letters of Support
    - Mentor(s) – if any
    - Co-Investigator(s) – if any
  - IRB Approval Letter (required)

## 2.2. Application Mailing Address

Submit the electronic (PDF) application to [https://stanfordmedicine.qualtrics.com/SE/?SID=SV\\_dgwLPnYbbFcETNb](https://stanfordmedicine.qualtrics.com/SE/?SID=SV_dgwLPnYbbFcETNb). Do not send any paper copies.

## 3. Preparing the Research Proposal

### 3.1. Face Page

#### Item 1. Title of Project

**Do not exceed 100 characters, including spaces and punctuation.** Choose a descriptive title that is specifically appropriate. A Resubmission application should normally have the same title as the previous grant or application. If the specific aims of the project have significantly changed, choose a new title.

#### Item 2. Resubmission Application

Check “No” if this is an original new (i.e. never submitted) application to Stanford CHRI.

Check “Yes” if this is a resubmission of a previously submitted Stanford CHRI application (e.g. Innovations in Patient Care).

#### Item 3. Type of Project

Select the nature of the research project. (e.g. Basic, Clinical or both)

#### Item 4. Principal Investigator (PI)

#### Name of Principal Investigator (PI) and Degree(s)

Name the one person responsible for the scientific and technical direction of the project. The PI is responsible for the research idea, development methods, supervision and conduct of the study. Indicate up to three (3) academic and professional degrees, or credentials, such as licenses (e.g., R.N.).

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## **Rank**

Check the academic title of the PI (e.g. Clinical Assistant Professor, Clinical Associate Professor, or Clinical Professor).

## **Department, Division**

Indicate the department and the division, if applicable, of the PI.

## **Telephone, SUNet ID, and Email Address**

Provide a daytime telephone number (cell phone preferred), SUNet ID, and the appropriate e-mail address (not a website URL).

## **Research Mentors**

Name up to three (3) research mentors and provide their emails. An NIH Biosketch (with Personal Statement) must be submitted for every mentor named. The NIH Biosketch template can be obtained here: <http://grants1.nih.gov/grants/funding/phs398/phs398.html> A letter of support is required for all mentors. Attach these in the Supporting Documents.

## **Co-Investigators**

Name up to three (3) Co-Investigators involved in this project. An NIH Biosketch must be submitted for every Co-Investigator named. A letter of support is required for all Co-Investigators. Attach these in the Supporting Documents.

## **Item 5. Total Costs Requested**

From the Budget Form Page, enter the "Total Costs." Total Costs must not exceed \$25,000. Total Costs must include the 8% infrastructure charge (ISC) taxed by Stanford University on all gift funds.

## **Item 6. Department Financial Manager to be notified if Award is made**

Provide the name and contact of the PI's department/division financial manager to be notified if an award is made.

## **Item 6a. Oracle Financial Org Code for the Award**

Ask the Departmental Financial Manager for the 4-letter organizational code for the PI's department/division (e.g., WXYZ).

## **Item 7. Biostatistics Consultation (required)**

Check "Spectrum" if a biostatistics consultation was provided by Spectrum. Check "Pediatrics" if a biostatistics consultation was provided by Pediatrics. "Other" if the consultation was not provided by either Pediatrics or Spectrum.

## **Item 8. Spectrum Child Health (SCH) Clinical Research Coordinator Services**

Check "No" if SCH clinical research coordinator and/or research nurse is not requested. Consult SCH if applicant needs advice on whether a research coordinator/nurse will be needed for the proposed project or would like more information about this service.

Check "Yes" if a SCH clinical research coordinator and/or research nurse is needed for the proposed project. Contact Spectrum Child Health to request coordinator services.

## **Item 9. Project Funding Status**

Indicate the funding status of the proposed project. List all that apply in the Budget Worksheet.

- Not funded: proposed project is not, and will not be, funded by any other source.
- Partially funded: proposed project may be partially funded by another source.

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- Funding pending: the proposed project has been submitted to other funding source(s) and may be potentially funded, in part or in full, by other internal or external sources.
- Funding approved: the proposed project has been approved for funding.
- Industry-sponsored: proposed project may be funded by industry sponsor.
- Foundation: proposed project may be funded by foundation sources.
- Mentored award: proposed project may be funded by a mentored award.
- Departmental: proposed project may be funded by departmental sources.
- Other: proposed project may be funded by other sources not listed above.

### **Item 10. External Funding Agencies**

The PI will also list in their proposal a minimum of two external funding agencies to which an application for subsequent funding will be submitted.

### **Item 11. Keywords**

Please enter 3-5 keywords separated by semicolons, for example “biomarker; acute kidney injury; stem cell.” Each individual keyword may be up to 100 characters in length i.e. “whole genome sequencing.”

Keywords should be present within the application.

### **Item 12. Project Summary**

Do not exceed 200 words. Write a succinct and accurate description of the proposed work. State the application's broad, long-term objectives and specific aims, making brief reference to the child and/or maternal health relatedness of the project (i.e. relevance to the mission of the Stanford Child Health Research Institute). Describe concisely the research design and methods for achieving the stated goals. This section should be informative to others, such that a medical faculty member who is not a specialist in your field, will understand. Avoid describing past accomplishments and the use of the first person.

## **3.2. Budget**

Insert a study budget using the **Budget Worksheet** downloadable at  
<http://spectrumchildhealth.stanford.edu>.

If awarded, the final budget may be developed in collaboration with Spectrum Child Health.

### **PI Salary Support**

A *Budget Justification* must be provided for requesting salary support and how the proposed work will be completed if the entire CHRI budget is allocated for PI salary.

### **Personnel**

*Name.* Starting with the PI, list the names of individuals who are involved on the project during the 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. Provide a brief budget narrative for ALL personnel by position, role, and percentage FTE.

*Totals.* Calculate the totals for each position and enter the subtotals in each column where indicated. The 8% ISC charge on the Budget Form is already a formula and is pre-calculated for you.

### **Non-personnel**

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**Supplies.** Itemize supplies in separate categories. List amount requested and justify each purchase.

**Patient Care Costs.** If inpatient and/or outpatient costs are requested for research with human subjects, provide the amounts requested. Make sure costs reflect Stanford/LPCH/SHC negotiated research discount rates. Check the [Spectrum Billing and Budget Workbook](#) for research discounted prices. 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. If you need help with the Spectrum Billing and Budget Workbook, please email [studyfacilitator@stanford.edu](mailto:studyfacilitator@stanford.edu) for assistance.

Provide specific information regarding anticipated sources for patient care costs, e.g., third party recovery or pharmaceutical companies. Include any potential or expected utilization of the Stanford Clinical and Translational Research Unit (CTRU) or Spectrum resources.

### Other Expenses

Itemize any other expenses by category and unit cost. These might include patient participation incentives, etc.

### Unallowable costs

The following items are **not** allowable:

- Laboratory-based-only research
- Travel, conference fees, tuition, classes
- Computer equipment or software
- Capital equipment
- Office supplies, ITSS communication
- Poster presentations, abstract submissions
- Any other indirect research costs

### Budget Worksheet and Budget Justification

The applicant must submit a Stanford CHRI Budget Worksheet detailing all current and potential other sources of funding for this study. Include a PDF of the Budget Worksheet in the Application as well as submit the Excel document. The Stanford CHRI Budget Worksheet is available at:  
<http://spectrumchildhealth.stanford.edu>.

List all potential sources of active or pending funding. Active funding is research project awarded and not expired. Pending funding is research project submitted but not awarded or rejected.

Indicate the funding agency/source, submission date, direct cost amount, and funding status (e.g. awarded, pending, planned submission, rejected, etc.). Only include sources of funding relevant to this project.

### 3.3. Introduction (Resubmission Applications Only)

Include an Introduction **only** if this is a Resubmission Application. Summarize the substantial additions, deletions and changes to the application. The Introduction must also include a response to the issues and criticism raised in the Reviewer Comments. The Introduction may not exceed two (2) pages. All format requirements apply. See 1.3 "Resubmission Applications" for detailed instructions for current cycle round or future award cycles.

## **3.4. Research Plan**

Do not exceed 4 pages.

### **3.4.1. Specific Aims**

List the broad, long-term objectives and the goal of the specific research proposed, e.g., to test a stated hypothesis, create a novel design, solve a specific problem, challenge an existing paradigm or clinical practice or address a critical barrier to progress in the field.

### **3.4.2. Relevance to Child and/or Maternal Health**

Using no more than two or three sentences, describe the relevance of this research to child and/or maternal health. In this section, be succinct and use plain language that can be understood by a general, lay audience. The Stanford CHRI defines “child and/or maternal health” as referring to the expectant mothers, oocyte, zygote, embryo, fetus, infant, child, and adolescent (under the age of 21 years of age).

### **3.4.3. Background and Significance**

Briefly sketch the background leading to the present application, critically evaluate existing knowledge, and specifically identify the gaps that the project is intended to fill. State concisely the importance and health relevance of the research described in this application by relating the specific aims to the broad, long-term objectives. If the aims of the application are achieved, state how scientific knowledge or clinical practice will be advanced. Describe the effect of these studies on the concepts, methods, technologies, treatments, services or preventative interventions that drive this field.

### **3.4.4. Preliminary Studies (if available)**

Use this section to provide an account of the principal investigator's preliminary studies pertinent to this application, including his/her preliminary experience with and outreach to the proposed racial/ethnic group members.

### **3.4.5. Research Design and Methods**

Describe the research design conceptual or clinical framework, procedures, and analyses to be used to accomplish the specific aims of the project. Include how the data will be collected, statistically analyzed, and interpreted. Describe any novel concepts, approaches, tools, or technologies for the proposed studies. A tentative sequence or timetable for the project may be included here. For Clinical studies, include inclusion/exclusion criteria and sample size determination. A pre-award biostatistical consultation is required for all human-based studies. Describe a data and safety monitoring plan if a data safety monitoring board is involved.

### **3.4.6. Career Development**

Describe briefly how this funding will contribute to PI's career goals. Describe this project's potential to meet the Stanford CHRI criteria:

1. Produce abstracts, publications, or presentations resulting from the project.
2. Lead to external funding.

### **3.4.7. Potential Pitfalls and Contingency Plans**

Describe the potential pitfalls and limitations for your project and discuss alternative approaches to achieve the project aims.

### **3.4.8. Future Steps**

Define follow-up work, long-term sustainability, and how this project will lead to new opportunities for research funding.

## **3.5. Appendix**

Do not exceed 3 pages. Include figures and references in the Appendix section.

## **3.6. Supporting Documents**

**NIH Biographical sketches.** An NIH Biosketch or CV is required for the applicant.

See NIH Biosketch format and sample at <http://grants1.nih.gov/grants/funding/phs398/phs398.html>

**Letters of Support.** Attach all letter(s) of support here. Letters of support are ***not blinded*** and must not be sent separately. Include them as an integral part of the application package in electronic PDF format.

**IRB Approval Letter.** Attach the IRB approval letter here. Do *not* attach the entire e-protocol.

IRB approval of the proposed research is required prior to application submission. To help determine whether research that involves the use of human data or biological specimens is human subjects research, refer to <http://humansubjects.stanford.edu/>.

## **4. The Peer Review Process**

### **4.1. Overview**

The peer-review process outlined here is modeled after the NIH. It is intended to ensure that applications are evaluated fairly, equitably, timely, and conducted in a manner free of bias. Each application is assigned a primary and a secondary reviewer. Before the review meeting, each reviewer assigned to an application will give a preliminary impact score for that application based on the five review criteria (see below).

See [http://grants.nih.gov/grants/peer/guidelines\\_general/scoring\\_system\\_and\\_procedure.pdf](http://grants.nih.gov/grants/peer/guidelines_general/scoring_system_and_procedure.pdf)

### **4.2. Scoring**

Reviewers are instructed to evaluate research applications by addressing the five core review criteria (see below) and the project's relevance to child and maternal health. For each application that is discussed, a final overall impact score will be given by each review committee member (without conflicts of interest) following the panel discussion. Each member's impact score will reflect his/her evaluation of the overall impact of the project in its entirety, rather than an arithmetic formula applied to the reviewer's scores given to each criterion. The final impact score for each discussed application will be determined by calculating the arithmetic average of all the eligible members' impact scores, and multiplying the average by 10. Scores >69 will be given to applicant as "NA".

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All applicants will receive a written critique, called Reviewer Comments, regardless of award and are given the opportunity to address reviewer comments. The Reviewer Comments represents a combination of the reviewers' written comments and scores for individual criteria.

### 4.3. Evaluation Criteria

**Overall Impact.** Reviewers will provide an overall impact/priority score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following five core review criteria, and additional review criteria (as applicable for the project proposed).

**Core Review Criteria.** Reviewers will consider each of the five review criteria below in the determination of scientific and technical merit, and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have major scientific impact. For example, a project that by its nature is not innovative may be essential to advance a field.

**Significance.** Does this study address an important issue related the health of children and expectant mothers? If the aims are achieved, how will they advance scientific knowledge or clinical practice? What will be the effect of this study on the concepts, methods, technologies, treatments, services, or preventions that drive this clinical practice?

**Approach.** Are the conceptual or clinical framework, design, methods, and analyses adequately developed, well integrated, well-reasoned, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics?

**Innovation.** Is the project original and innovative? For example: Does it challenge existing thought or clinical practice or address an innovative hypothesis or critical barrier to progress in the field? Does the project develop or use novel concepts, approaches, methods, tools, or technologies?

**Investigators.** Are the investigators appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the principal investigator and other researchers? Does the investigative team bring complementary and integrated expertise to the project (if applicable)?

**Environment.** Does the clinical and scientific environment contribute to the probability of success? Do the studies benefit from unique features of the clinical and scientific environment or subject populations or use useful collaborative arrangements? Is there evidence of institutional support?