

Instructions for the following programs:

Clinician Educator (CE) Grants

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1. General Instructions

1.1. Introduction

These instructions pertain to applications for the Stanford Maternal and Child Health Research Institute (MCHRI) Clinician Educator (CE) Grant. For detailed program policies, please refer to the <u>MCHRI</u> <u>website</u>.

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.
- Use black ink that can be clearly copied.
- Print must be clear and legible.

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, except for the PI's last 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.

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.

Grantsmanship

- Please keep in mind that most reviewers are *not* likely to be an expert in your field.
- 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.
- Avoid the use of acronyms and technical terms.

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.

Page Limits

Observe the page number limits provided in the table below.

SECTION OF APPLICATION	PAGE LIMITS
Face Page	1 page
Budget Worksheet	1 page
Introduction (Resubmissions only)	2 pages
Lay Summary	<u>≺</u> 300 words
DEIJ statement	<u><</u> 300 words
Research Plan *UPDATED*	3 pages
Appendix ** (figures and references)	3 pages
NIH Biographical Sketch (per person)	5 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 during Current Award Cycle

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.

Applicants are encouraged to meet with a MCHRI reviewer to discuss revisions and suggestions for improvement prior to resubmission. Contact MCHRI Administration (<u>mchri admin@stanford.edu</u>) to request a resubmission consultation with a reviewer.

1.4. 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)*.

The original application is kept intact; any application material sent post-submission is sent separately to reviewers. 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)
- 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)

Unacceptable post-submission materials include:

- Updated Specific Aims or Research Plan pages
- News of an article accepted for publication (this is not allowed due to the short turnaround time in our review process. If in press, please make sure to properly reference them on your NIH Biosketch.
- Late-breaking research findings
- Supplemental pages information not contained in the existing application
- 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 Application Instructions on font size, margins, and paper size
- Additional pages such as budget, biographical sketches, and other required forms must follow MCHRI page limit requirements

The deadline for receipt of additional materials is one month (30 calendar days) prior to the peer review meeting. Contact MCHRI 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 by after a peer review of a grant application has been completed and prior to funding, the applicant will be notified by email.

1.5. Application Submission, Late Applications

The electronic (PDF) application *must* be received by MCHRI Administration via the <u>ONLINE</u> <u>APPLICATION PORTAL</u>, no later than 11:59 PM PT on the submission deadline specified in the **RFA**. In addition to including the Budget worksheet in the electronic (PDF) application it must also be submitted as a separate Excel document. Incomplete applications will not be accepted and all applications must be submitted with all required documents.

Late applications. Permission is not granted in advance for submission of a late application. Late applications are not accepted.

Application Assignment Information

Competing grant applications submitted to MCHRI will be processed through MCHRI Administration. The application will be assigned to an appropriate MCHRI 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 MCHRI 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 investigators must direct all questions to MCHRI Administration.

1.6. Resources for Finding Help

If after reviewing these application instructions, help is needed in preparing the application, contact MCHRI Administration at <u>mchri_admin@stanford.edu</u> or calling 650-724-0279. Our <u>FAQ page</u> is also a great resource.

2. Submission of the Grant Application

Submit a complete application. The application must be complete and accurate at the time of submission. Applications will 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 Budget in Excel format in a separate document. Submit the following materials into **one** PDF document. Collate application materials in this order:

- Face Page (maximum 1 page)
- Budget include a PDF of the budget in your document
- Introduction (Resubmissions Only; maximum 2 pages)
- Lay summary (300 words or less)
- *NEW* diversity, Equity, Inclusion and Justice (DEIJ) statement (300 words or less)
- Research Plan (maximum 3 pages)
 - o Specific Aims
 - Project Timeline
 - Relevance to Maternal and Child Health
 - o Background and Significance
 - o Preliminary Studies (if available)
 - Research Design and Methods
 - Human Subject Research Feasibility (if applicable)
 - Contacted SMCH Clinical Research Support Office (if applicable)
 - o Career Development (Pilot Grant Category I only, Instructor and Assistant Professor)
 - o Potential Pitfalls and Contingency Plans
 - Future Steps
- Appendix (Figures and References; maximum 3 pages)
- Supporting Documents
 - Applicant Information
 - NIH Biosketch (maximum 5 pages per person)
 - Supervisor/ Primary Research Mentor Information
 - Mentor form to be completed online (required for Clinical Instructor and Clinical Assistant Professor rank) Do not include a separate letter of support from your mentor (note there is a new DEIJ questions.
 - NIH Biosketch (maximum 5 pages per person)
 - Non-Primary Mentor Information (if applicable)
 - Letter of Support per non-primary mentor
 - NIH Biosketch (maximum 5 pages per person)

- Co-Investigator/Collaborator Information (if applicable)
 - Letter of Support per collaborator and/or co-investigator
 - NIH Biosketch (maximum 5 pages per person)
- IRB Approval (if applicable)
 - Include confirmation of IRB submission and the date (mm/dd/yy) of the scheduled IRB review meeting
 - If the IRB has already been approved, include a copy of the IRB approval letter
 - If exempt, state that the proposal is exempt from human subjects research

3. Preparing the Research Proposal

3.1. Face Page

Please complete the application using the provided face page as formatted and use the accompanying checklist.

3.2. Budget

Use Budget Worksheet and include appropriate expenditures as directed in individual program policy. If other sources of funding exist, briefly describe. Please include a PDF of the budget worksheet with your proposal.

3.3. Introduction (Resubmission Applications Only)

Proposals that were not funded are allowed one resubmission in another cycle as long as all other eligibility criteria are met.

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. Lay Summary

Briefly and clearly provide the rationale and objective for the proposed research project in a manner readily understood by a general audience. Avoid using acronyms, jargon, or technical, field-specific terminology. Should not be more than 300 words.

3.5 Diversity, Equity, Inclusion and Justice (DEIJ) statement

In what ways have you contributed towards and/or demonstrated a commitment to inclusion, equity, and diversity through your academic career, and how do you plan to advance these commitments professionally? Should not be more than 300 words.

3.6 Research Plan

Do not exceed 3 pages.

3.6.1 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, address a critical barrier to progress in the field, or develop new technology.

3.6.2 Project Timeline

Please include a detailed timeline of milestones. Applicants must propose one or more milestones for each specific aim. Include milestones for each year of potential funding.

3.6.3 Relevance to Maternal and Child Health

Using no more than two or three sentences, describe the relevance of this research to maternal and child health. In this section, be succinct and use plain language that can be understood by a general, lay audience. The MCHRI defines "child health" as referring to the expectant mother, oocyte, zygote, embryo, fetus, infant, child, and adolescent (under the age of 18 years of age).

3.6.4 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.

3.6.5 Preliminary Studies (if available)

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

3.6.6 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. For Clinical studies, include inclusion/exclusion criteria and sample size determination. *UPDATE* For human-based studies, there should be a brief description of sample size and plan for statistical analyses of the results. The study design must include a description and rationale for the composition of the proposed study population with respect to sex/gender, race and ethnicity, including a recruitment strategy for the study population. A pre-award biostatistics consultation is required for all human-based studies. Describe a data and safety monitoring plan if a data safety monitoring board is involved. Studies involving patients at Stanford Medicine Children's Health (SMCH) must contact the SMCH Clinical Research Support Office *early in the study design phase* by emailing crso@stanfordchildrens.org to ensure hospital units involved can assess feasibility and resource requirements are taken into consideration.

3.6.7 Career Development

Please describe how this funding will contribute to applicant's career goals and their path to an independent investigator. Describe the plan to achieve these goals and include future grant submissions.

This section is not required for Pilot Grants New Idea category. However, a justification for the New Idea category is **required** in lieu of the career development section.

3.6.8 Potential Pitfalls and Contingency Plans

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

3.6.9 Future Steps

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

3.7 Appendix

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

3.8 Supporting Documents

Please include as directed in 2.1 Bindings and Packaging