



## STANFORD MATERNAL AND CHILD HEALTH RESEARCH INSTITUTE

### Clinician Educator Support Policy

#### GENERAL

The Stanford Maternal and Child Health Research Institute (MCHRI) Clinician Educator (CE) Grant Support Program aims to encourage, develop, and support CEs to pursue impactful and meaningful clinical research for the area of proposed work. Applications may include involvement of other Allied Health Professionals.

#### MISSION

The Clinician Educator Grant Support Program seeks innovative, well-developed proposals that pursue clinical research relevant to their clinical practice related to the health of expectant mothers and children<sup>1</sup>. Clinical research is defined by the NIH as research with human subjects that is:

- Patient-oriented research:
  - Research conducted with human subjects (or on material of human origin such as tissues, specimens, and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. It includes: mechanisms of human disease; therapeutic interventions; clinical trials; development of new technologies
- Epidemiological and behavioral studies
- Outcomes research and health services research

#### DIVERSITY, EQUITY, INCLUSION and JUSTICE (DEIJ)

MCHRI is committed to advancing diversity, equity, inclusion, and justice in all aspects of our work supporting research, education and resources in maternal and child health. Applicants will be asked to provide a DEIJ statement in their application.

#### ELIGIBILITY

- All Clinician Educators (CE) at the rank of Clinical Instructor or above can apply
- All applicants must have or plan on having a focus on maternal child health research, or wish to expand their interest in maternal child health research
- All applicants must continue to be appointed at the Clinical Instructor rank or above for the duration of the award, including any extensions.
- A *Primary Research Mentor* is required for Clinical Instructors & Clinical Assistant Professors.
- A Mentor Support Form is *required* from the *Primary Research Mentor* for Clinical Instructors & Clinical Assistant Professors. Upon creation of an Online Application Record by the applicant, the *Primary Research Mentor* will receive an automated email with a unique link to complete the Mentor Support Form. For further instructions on the Mentor Support Form please go [here](#). Applicants should not include a letter of support from their mentor in lieu of or in addition to the online support form.
- The applicant and mentor are required to be [MCHRI Member](#) to apply for this grant. The mentor should be at the Associate Professor or Professor rank with a track record as a research mentor.
- Projects must be novel to the field and can be a continuation or expansion of the investigator's current research.

The following are *not* eligible:

- Visiting scholars to Stanford
- Lab-based only or animal studies

#### AWARD

Total award is up to **\$35,000** for a period of 12 - 18 months. **One** proposal per applicant is accepted each cycle.

*Award may be used for:*

- PI salary to secure time off from clinical duties
- Research personnel

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<sup>1</sup> "Children" or "Child" refers to expectant mothers, oocyte, zygote, embryo, fetus, infant, child, and/or adolescent.

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- Supplies and ancillary services necessary for project
- Statistical support

Award may ***NOT*** be used for:

- Laboratory-based-only research
- Travel, conference fees, tuition, classes
- Computer equipment (e.g. iPads, laptops, tablets, smartphones and other similar technologies) or software unless directly and primarily benefitting the project
- Capital equipment
- Office supplies, ITCC communication
- Poster presentations, abstract submissions
- Any other indirect research costs including sub-recipient Facilities and Administrative (F&A) costs

## Timeline

- Two competitions are offered annually (spring and fall)
- Anticipate a total review turnaround time of 10 weeks from the submission deadline

## Performance Period

The project proposed must be feasible to complete within 18 months.

## Determination of Funding Level

If the applicant is successful in obtaining external funding for their salary (Early Career category), or for non-salary costs (Early Career and New Idea categories), they must immediately notify MCHRI Administration. *In such a situation, the MCHRI award may be reduced by a comparable amount.*

## Submission and Award Limits

A single applicant may submit only 1 application per grant cycle. An investigator may not simultaneously hold more than one active MCHRI award of the same type.

## IRB Approval

IRB application must be submitted prior to the MCHRI application submission deadline and the IRB review meeting date stated in the MCHRI application. If there is an approval letter, it must be attached with the application. If awarded, the award cannot commence (fund transfer) without the IRB approval letter. For more information, please see: <http://humansubjects.stanford.edu/>

## Pre-Submission Support

The MCHRI Office of Community Engaged Research (OCEnR) is available for technical assistance with any CEnR components of an applicant's proposal. Please reach out directly to CEnR Manager, Dongmei Tan at [dongmei@stanford.edu](mailto:dongmei@stanford.edu) or through the [intake form](#).

Assistance with coordination and identification of other Stanford resources. To request support, contact [mchri\\_admin@stanford.edu](mailto:mchri_admin@stanford.edu) at least 30 days prior to submission deadline.

## No-Cost Extensions (NCX)

If the project is not completed within 12 months due to *unforeseen* circumstances, a no-cost extension (NCX) of up to 6 additional months may be requested (total study period not to exceed 24 months). Requests must be submitted at least thirty (30) days prior to the award end date. Requests are considered on a case-by-case basis. Not all requests are approved. Only one NCX is granted per project. Detailed instructions are available [here](#).

## MCHRI RESOURCES

### MCHRI Clinical Research Coordinator Services

The award may be applied towards Research Coordinator Services to assist with any or all of the following: IRB applications, regulatory document completion, identification of eligible subjects, recruitment, enrollment, clinical data collection or sample acquisition, specimen handling/shipping, quality control, adverse event reporting, data entry, oversight of regulatory compliance, etc. Contact [MCHRI](#) to request coordinator services.

### MCHRI Drug & Device Development (D<sup>3</sup>) Services

The MCHRI Drug & Device Development Service was established to provide direct assistance to investigators in every stage of medical product development. Ensuring the project is on track, is targeting a robust market, and inclusive of all elements for regulatory approval are critical fundamentals which serve to expedite the translation of a health technology into the clinical setting. For investigators submitting MCHRI grant applications and interested in utilizing the service, please submit a request via the [service request form](#).

## PROPOSAL REQUIREMENTS

### Biostatistical Analysis

A statistical analysis plan is *required* for all human-based studies and those with power calculations.

As part of a partnership with the Stanford Quantitative Sciences Unit (QSU), MCHRI grant applicants may request data sciences resources as needed to support the success of their research project. Their expertise is available for study design, the development of grant proposals, and implementation of funded projects. The QSU will hold office hours for MCHRI applicants. Click [here](#) to submit a request directly to the QSU. Request QSU Office Hours at least 8 weeks in advance of a submission deadline. The QSU may not be able to

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accommodate Office Hours requests within the 8-week window.

## Clinical Research Support Office - Patient Oriented Research at SMCH

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](mailto:crso@stanfordchildrens.org) to ensure hospital units involved can assess feasibility and resource requirements are taken into consideration, including hospital costs. Studies that would occur at SMCH without CRSO consultation will not be reviewed or may be asked to resubmit in the next cycle.

## Community Engaged Research

Proposed projects with CEnR components should consult with MCHRI OCEnR prior to submission (see above under pre-submission support).

## PI Salary Support

*Instructors and Assistant Professors must provide a Budget Justification* for requesting salary support and how the proposed work will be completed if the entire MCHRI budget is allocated for PI salary (noting sources of non-salary support).

## Mentor Support Form

- A Mentor Support Form is *required* from the *Primary Research Mentor* for instructors & assistant professors. Upon creation of an Online Application Record by the applicant, the *Primary Research Mentor* will receive an automated email with a unique link to complete the Mentor Support Form. For further instructions on the Mentor Support Form please go [here](#). Applicants should not include a letter of support from their mentor in lieu of or in addition to the online support form.
- The applicant and mentor are required to be a MCHRI Member to apply for this grant. ***The mentor should be at the Associate Professor or Professor rank with a track record as a research mentor.***

## Letters of Support

- Letters of support are *required* from all listed *non-primary* research mentor(s), co-investigator(s) and collaborator(s).
- Letters are *NOT* blinded and must be attached at the end of the single, PDF application that is uploaded to the [Online application portal](#).

## Biosketch

A NIH Biosketch (including Personal Statement) from the applicant, *each* research mentor, co-investigator and collaborator must be obtained. The NIH Biosketch template can be obtained here: <https://grants.nih.gov/grants/forms/biosketch.htm>

## Budget and Budget Justification

The applicant must submit a [MCHRI Pilot Grants Budget Worksheet](#) detailing all current and potential other sources of funding for this study. Please contact [mchri\\_admin@stanford.edu](mailto:mchri_admin@stanford.edu) if you would like an administrative review of your preliminary budget.

Applicants must identify all potential sources of funding as instructed on the budget form and whether there is any overlap. If the potential sources of funding are not fully and clearly described, the proposal will not be reviewed, or the review may be negatively impacted.

## REVIEW CRITERIA

Review is based on (1) relevance to maternal and child health and (2) NIH Investigator-initiated Review Criteria:

1. *Significance.* Does this study address an important [maternal and child<sup>1</sup> health] problem? If the aims are achieved, how will scientific knowledge or clinical practice be advanced? What will be the effect of these studies on the concepts, methods, technologies, treatments, services, or preventions that drive this field?
2. *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?
3. *Innovation.* Is the project original and innovative? For example: Does it challenge existing paradigms 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?
4. *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)?
5. *Environment.* Does the scientific environment contribute to the probability of success? Do the studies benefit from unique features of the scientific environment or subject populations or use useful collaborative arrangements? Is there evidence of institutional support?

## SELECTION PROCESS

Proposals are reviewed by a MCHRI Scientific Review Committee.

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Successful proposals should demonstrate the potential to meet the following criteria:

- Produce abstracts, publications, or presentations resulting from the project
- Lead to external funding

## Reviewer Comments

All applicants receive reviewer comments regardless of award and given the opportunity to address reviewer comments.

## AWARDEE RESPONSIBILITIES

The PI will take responsibility for the research idea, development methods, IRB approval, supervision and conduct of the study in addition to the following:

- Award recipients will be required to complete a PDRF in SeRA upon notice of award approval and link applicable e-protocols.
- Award recipient and their division/department is responsible for coordinating the transfer of funds to subrecipients, if applicable.
- Submit a timely [Progress Report](#) *within 30 days of the award end date*
- Provide updates in all Progress Reports on funding status from external and/or internal sources
- Submit [progress reports](#) for up to 3 years following the award end date that will include information about grants submitted, publications, employment, and new external funding resulting from this award
- Acknowledge research support in all publications, abstracts, and presentations as follows:

*"The project described in this publication was supported by the by the Stanford Maternal and Child Health Research Institute."*

Award recipients, who have not acknowledged their work, as indicated above, are not eligible for future awards sponsored by the MCHRI.

## RESUBMISSION

Applicants not funded may resubmit proposals for future cycles and are encouraged to work with the members of the Review Committee on revisions and/or suggestions for improvement. To be respectful of our reviewers time commitments all requests must be submitted at least one month (4 weeks) prior to application due date. A maximum of one (1) resubmission is accepted. To request a resubmission consultation with a reviewer, contact [mchri\\_admin@stanford.edu](mailto:mchri_admin@stanford.edu).

## CONTACT

MCHRI Administration:  
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