Pilot Grants Policy

GENERAL

The Stanford Maternal and Child Health Research Institute (MCHRI) Pilot Grants funds innovative maternal and child health-focused clinical and translational research in the following categories:

I. Pilot Early Career ($50K)
II. New Ideas ($50K)

All projects must be significantly related to the health of expectant mothers and children. The applicant can be any practitioner or scientist who has a focus on maternal or child health 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.

GENERAL ELIGIBILITY

- All applicants must have, or plan on, having a focus on maternal child health research.
- All applicants and their mentors must be MCHRI Members.
- A Primary Research Mentor must be identified for instructors and assistant professors.
- All applicants must continue to be appointed at the Instructor rank or above for the duration of the award, including any extensions.

The following are not eligible:

- Clinician Educators (see CE Grants Program).
- Visiting scholars to Stanford
- Adjunct Faculty.
- Senior Research Scientists, Research Associates/Assistants.

- Former recipients of MCHRI sponsored awards who have not complied with award/reporting requirements.
- Mentor or applicants who have not cleared overdraft(s) in previous MCHRI awards prior to applying.

Eligibility Summary

<table>
<thead>
<tr>
<th>Category</th>
<th>Instructor</th>
<th>Asst. Prof.</th>
<th>Assoc. Prof.</th>
<th>Professor</th>
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</thead>
<tbody>
<tr>
<td>Early Career</td>
<td>●</td>
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<tr>
<td>New Idea</td>
<td>●</td>
<td>●</td>
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CATEGORIES

I. Pilot Early Career Investigators

Eligibility: Instructors & Assistant Professors only

The Pilot Early Career category provides both PI salary and non-salary support for hypothesis-driven or hypothesis-seeking research that could lead to research that is externally fundable as a result of the proposed study. The study must be a pilot, concept, development, or feasibility proposal. This category is intended to help early-career applicants become independent researchers by facilitating projects that will produce the data needed for applications to external funding agencies. This mechanism is not intended for trainees.

II. “New Ideas” for Mid/Senior Investigators

Eligibility: Associate Professors & Professors only

The New Ideas category provides non-PI-salary support for high-impact, high-risk projects proposed by mid to senior investigators. Projects must be novel to the field (i.e., not previously described in literature) and not a continuation or expansion of the investigator’s currently funded or unfunded research. The grant is intended to facilitate projects, which are highly innovative and, if successful, will facilitate novel directions in research that is fundable by external funding agencies.

1 “Children” or “Child” refers to expectant mothers, oocyte, zygote, embryo, fetus, infant, child, and/or adolescent.
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AWARD

Award may be used for:

<table>
<thead>
<tr>
<th></th>
<th>PI Salary</th>
<th>Research Personnel</th>
<th>Research Supplies / Services</th>
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</thead>
<tbody>
<tr>
<td>Early Career</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>New Idea</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>

Award may NOT be used for (all categories):
- Travel, conference fees, tuition, classes
- Membership dues, journal subscriptions, books
- Office supplies, ITCC communications
- Poster presentations, abstract submissions
- Computer equipment (e.g., iPads, laptops, tablets, smartphones, and other related technologies), software, or accessories unless directly and primarily benefiting the project
- Any other indirect research costs including subrecipient 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.

No-Cost Extensions (NCX)
If the project is not completed within 18 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.

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 IRB 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 REQUIREMENTS

MCHRI Resources
Consultations with all applicable MCHRI resources described in this section are required prior to submission at least 6-8 weeks before the deadline. For assistance with coordination of MCHRI and/or other Stanford resources, contact MCHRI Administration at mchri_admin@stanford.edu at least 6-8 weeks prior to submission deadline.

MCHRI Clinical Research Support Office (CRSO) for Patient Oriented Research at SMCH
Studies involving patients at Stanford Medicine Children’s Health (SMCH) must contact CRSO early in the study design phase or at least 8 weeks prior to submission by emailing 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.

MCHRI-Funded QSU Biostatistical Support
A statistical analysis plan is required for all human-based studies and all projects requiring power calculations. Through our funded partnership with the Quantitative Sciences Unit (QSU), MCHRI grant applicants may request data sciences resources to support the success of their research project, the development of grant proposals, and implementation of funded projects. The QSU provides expertise in study design, database creation, data management and analysis. The QSU will hold consultations for MCHRI applicants. Click here to submit a request directly to the QSU. Request QSU Consultation at least 8 weeks in advance of a submission deadline. The QSU may not be able to accommodate consultation requests within the 8-week window.

MCHRI Office of Community Engaged Research (OCEnR)
Proposed projects with Community Engaged Research components are required to consult with OCEnR 4-6 weeks prior to submission. OCEnR provides technical assistance with any CEnR components of applicant’s proposal. To
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request assistance, contact OCEnR Manager, Dongmei Tan at dongmei@stanford.edu or submit intake form.

MCHRI Clinical Research Coordinator Services
The award may be applied towards a MCHRI Clinical Research Coordinator 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. To request a consult for coordinator services, submit brief intake here.

MCHRI Drug & Device Development (D³) Services
D3 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, submit a request via the service request form.

PROPOSAL REQUIREMENTS

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. 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 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 child health and (2) NIH Investigator-initiated Review Criteria:

1. Significance. Does this study address an important [child\* 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 prevention 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 an MCHRI Scientific Review Committee.

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, 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 are responsible for coordinating the transfer of funds to sub-recipients, if applicable.
- Faculty and Instructors keep their Community Academic Profile (CAP) updated and utilize the “Permit PubMed import” feature.
- 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 Stanford Maternal and Child Health Research Institute."

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 the application due date. A maximum of one (1) resubmission is accepted. To request a resubmission consultation with a reviewer, contact mchri_admin@stanford.edu.

CONTACT
MCHRI Administration:
mchri_admin@stanford.edu
650-724-0279

MCHRI Admin Rev. 01/24