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 ($35K)
II. New Ideas ($35K)

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.

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.

The following are not eligible:

- Clinician Educators (see Clinician Educator Grants Program).
- Visiting scholars to Stanford.
- 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>
</tr>
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<tbody>
<tr>
<td>Early Career</td>
<td>Yes</td>
<td>Yes</td>
<td></td>
<td></td>
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<tr>
<td>New Idea</td>
<td>No</td>
<td>Yes</td>
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<td>Yes</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.

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.

AWARD

Award may be used for:

<table>
<thead>
<tr>
<th>Category</th>
<th>PI Salary</th>
<th>Research Personnel</th>
<th>Research Supplies / Services</th>
</tr>
</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, ITSS communications
- Poster presentations, abstract submissions

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1 “Children” or “Child” refers to expectant mothers, oocyte, zygote, embryo, fetus, infant, child, and/or adolescent.
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- Computer equipment (e.g. iPads, laptops, tablets, smartphones, and other related technologies), software, or accessories
- Any other indirect research 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 is 12 months for both categories.
- Awardee is required to submit a Progress Report at the end of the performance period and provide follow-up data for three additional years including grants-submitted and/or awarded, abstracts, presentations, and publications resulting from this award

Determination of Funding Level
If the applicant is successful in obtaining external funding for his/her salary (Early Career), or for non-salary costs (Early Career and New Idea), s/he 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 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 18 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.

IRB Approval (Approved Before Application)
IRB approval of the proposed research is required prior to application submission. IRB approval letter must be attached with application. For more information, please see: http://humansubjects.stanford.edu/

MCHRI Resources
The award may be applied towards a Clinical Research Coordinator and/or Research Nurse 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 Administration to request coordinator services.

Pre-Submission Proposal Review
Advice for proposal development is available from MCHRI reviewers. They can also assist with coordination and identification of other Stanford resources. To request a proposal review, contact mchri_admin@stanford.edu at least 30 days prior to submission deadline.

PROPOSAL REQUIREMENTS

Biostatistical Consultation
A biostatistical consult 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 services as needed to support the success of their research project (most services at no charge to the investigator). Their expertise is available for consultation, the development of grant proposals, and implementation of funded projects. Click here to submit a request directly to the QSU. Request QSU consults no later than 4 weeks prior to submission deadline.

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.

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 (we encourage applicants to create a record at least 4 weeks prior to submission deadline), 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.
- 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.
- A primary research mentor is not required for Associate Professor and Professor ranks. The Mentor Support Form is optional. However, if you select ‘yes’ when submitting your Online
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Application Record and choose to designate a primary research mentor, your mentor will be required to submit the Mentor Support Form.

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 and co-investigator must be obtained. The NIH Biosketch template can be obtained here: http://grants1.nih.gov/grants/funding/phs398/phs398.html

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.

Applicants must identify all potential sources of funding as instructed on the budget form. If the potential sources of funding are not fully and clearly described, the proposal will not be reviewed.

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 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 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:

- Faculty and Instructors keep their Community Academic Profile (CAP) updated and utilize the "Permit PubMed import" feature
- Submit reports in a timely manner, including a 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."

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 prior to application due date. A maximum of 2 resubmissions are accepted. Attach a Resubmission Summary of Changes (maximum 2 pages) after the Face Page. See the Application Instructions for details. To request a resubmission consultation with a reviewer, contact mchri_admin@stanford.edu.

CONTACT
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mchri_admin@stanford.edu
650-724-0279