STANFORD MATERNAL AND CHILD HEALTH RESEARCH INSTITUTE Bridge Support Policy

GENERAL

The Stanford Maternal and Child Health Research Institute (MCHRI) Bridge Support Program aims to provide maternal and child¹ health researchers up to 1 year of funding to aid in the continuation of independent investigator clinical and translational research projects (NIH R01 or NSF, DOD, or other equivalent award) so that progress may be made to obtain renewed or replacement funding. This funding mechanism is intended to bridge to R01 equivalent grants, or larger NIH grants, i.e., long term funding mechanism (not R21 to R21 or similar grants).

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, or plans to focus on, maternal or child health research.

Applicants pursuing this funding mechanism typically fall into one of the following categories:

- Unsuccessful first submission of a competitive renewal. Applicant must clearly address the concerns outlined in the summary statement.
- Unsuccessful submission of a new R01 proposal if:
 - New proposal represents replacement funding for a previous NIH funded line of investigation that has run its course; or
 - Applicant has completed a K08, K23, K12, or K01 grant, or an equivalent NIH K grant intended for transition to independence and has received a priority score on the original R01 submission.
- Unsuccessful (A1) resubmission of a competitive renewal or a new R01 (as outlined above) will be considered if:
 - Applicant received a strong priority score; and
 - Applicant describes how the summary statement will guide development of a new application.

ELIGIBILITY

- Only research projects supported (or in progress) by an independent investigator award (NIH R01 or NSF, DOD, or other equivalent award) will be eligible.
- Applicants must hold an appointment in the following lines within SoM or Stanford University: CE/UML/NTLR/NTLT/UTL.
- All appointees at the rank of Assistant Professor or above can apply.
- All applicants must have or plan on having a focus on maternal and child health research or wish to expand their interest in maternal and child health research.

The following are *not* eligible:

Visiting scholars to Stanford

IRB Approval

IRB application must be submitted <u>prior</u> to the MCHRI application submission deadline <u>and</u> 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 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 <u>required</u> for all humanbased studies and all projects requiring power calculations. Through our funded partnership with

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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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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 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 accommodate Office Hours requests within the 8-week window.

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.

APPLICATION CRITERIA

Application must include:

- Introduction (Maximum 1 page)
- Letter of Support from Department Chair indicating, if awarded, the Department will supply \$50K in matching funds (see AWARD)
- Letter of Support from Division Chief
- Summary statement from unsuccessful submission
- Applicants should include their response for the resubmission, showing that they already have the data to respond to the critiques and are ready to submit a revision.
- Budget Worksheet
- Include written support of the program project principal investigator (in the case of sub-projects with program projects – P01, P50, SCOR, etc.)
- If the applicant holds an active MCHRI Faculty Scholar Award, please describe how the proposed Bridge award overlaps with the

existing Faculty Scholar funding or other MCHRI funded-partner grants. Clearly state if there is no overlap.

AWARD

Total award is up to **\$100,000** (\$50,000 from the MCHRI and \$50,000 cost shared from the applicant's department) for one year. **One** proposal per applicant is accepted each cycle.

Award may be used for:

- Research personnel
- Supplies and ancillary services necessary for project.
- Statistical support
- Computer software (must be justified)

Award may NOT be used for:

- PI Salary (Department is required to provide support)
- Travel, conference fees, tuition, classes
- Computer equipment (e.g., iPads, laptops, tablets, smartphones, and other similar technologies)
- Capital equipment
- Office supplies, ITSS communication
- Poster presentations, abstract submissions
- Any other indirect research costs

Performance Period

MCHRI Bridge Support is for *no longer than 12 months*. Should renewed or replacement funding be awarded prior to bridge funding end date, the awardee is required to notify MCHRI Administration and return any unexpended funds. The start date can be no later than three months after the award announcement date.

Review Timeline

- Three grant cycles are offered annually (September, January & May)
- Proposals are reviewed within 3-4 weeks of the submission deadline.
- Awards are announced 4-5 weeks from the submission deadline.

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 [child¹ 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,

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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, clinical practice, 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, subject populations, or use useful collaborative arrangements? Is there evidence of institutional support?

SELECTION PROCESS

Proposals will be reviewed by the MCHRI Directors.

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

- Significance of the research and maternal child health relevance
- Project's past productivity, external review assessment, track record in area, and appropriateness of the budget; and
- Project's likelihood of funding within the next appropriate funding cycle.

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:

- 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.
- 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.

TERM OF AWARD

All awardees are limited to a single award for <u>up to</u> 1 year. Should there be a change in the awardee's role that significantly alters their ability to fulfill their responsibilities, the award will be forfeited prior to the completion of the term. However, if there have been unusual occurrences then the awardee may request a deferral or leave of absence from the award; this request will be adjudicated by the Director of the MCHRI. If a deferral is approved, the end date of this award will be adjusted accordingly by MCHRI administration.

CONTACT

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

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