STANFORD MATERNAL AND CHILD HEALTH RESEARCH INSTITUTE Clinical (MD) Trainee Support Policy

GENERAL

The Stanford Maternal and Child Health Research Institute (MCHRI) Clinical (MD) Trainee Support program is designed to create a pathway and provide support for training the next generation of physician scientists focused on child¹ health.

All projects must be *significantly* related to maternal and child health. "Child" refers to the expectant mother, embryo, fetus, infant, child, and adolescent. All areas of research are eligible: basic, translational, clinical research, epidemiology/statistics, informatics, health services, or health policy.

Research Fellows of the MCHRI shall have roles and responsibilities consistent with MCHRI's Charter, Mission, Vision, and Values and use the resources for their remuneration and benefits such that there shall be demonstrable, significant, and meritorious scholarship/research activities related to innovation in maternal and child health.

The appointment of a MCHRI Research Fellow shall:

- 1. Involve a competitive process.
- 2. Recognize outstanding:
 - a. Performance and potential of the candidate
 - b. Accomplishments and track record of the mentor(s)
 - c. Research proposal
- Not entitle the nominee to additional benefits or compensation beyond those as determined by the Stanford School of Medicine (SOM) or Stanford Medicine Children's Health (SMCH) as appropriate.

Unless specified by the philanthropic gift agreement, the endowment for a MCHRI Research Fellow does not belong to any specific Department or Division, but rests within the MCHRI and is used in a manner that optimizes the use of these resources for innovation in child health.

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.

All applications must provide a plan for promoting inclusion, diversity, and equitable research in the research proposal. This section should describe the activities and strategies of the applicant to promote DEIJ within the context of the study population(s) and any associated research group(s).

ELIGIBILITY

To be eligible for the award, the applicant must meet these criteria:

- Hold a medical (MD or equivalent) degree.
- Have completed one year of training by the start of the award term.
- Clinical primary location for seeing patients is LPCHS.
- Demonstrate a commitment to an investigative academic career in obstetrics, pediatrics, pediatricsubspecialty or subspecialty primarily focused on child health (e.g., pediatric surgery)
- Use the MCHRI funding for their 2nd and 3rd years of research training (Post Graduate Year (PGY5 and PGY6) during which a minimum of 75% time is devoted to research²
- Have legal residence status in the United States
- Be a practitioner or scientist who has a focus on maternal or child health.
- Primary research mentor may be from any research discipline that is appropriate for the project.
- Primary research mentor must be a member of the MCHRI.
- Non-ACGME fellows are eligible provided all other criteria are met.

The following are *not* eligible:

may apply as long as equivalent criteria are met and there is a commitment from the Dept they will be accepted into the child health MD fellowship.

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

² Since there are some differences in the timing of research during the training of Pediatric subspecialists and other child health MD specialists (e.g. pediatric surgeons) the respective discipline's trainees

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 Mentor or applicants who have overdraft(s) in previous awards that are not cleared prior to applying.

PRE-SUBMISSION REQUIREMENTS

MCHRI Resources

Consultations with all applicable MCHRI resources described in this section <u>are required</u> 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 <u>required</u> 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 office hours for MCHRI applicants. Click here to submit a request directly to the QSU. Request QSU Office Hours atleast 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 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 request assistance, contact OCEnR Manager, Dongmei Tan at dongmei@stanford.edu or submit intake form.

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

Nomination

MCHRI Research Fellows will be nominated by their Division Chief or Department Chair. There is no limit to the number of fellows nominated per Division or Department.

The nominator's letter will verify that:

- The applicant will spend a minimum of 75% time devoted to research during the years funded by the MCHRI fellowship.
- And, that failure to maintain this commitment will result in forfeiture of the award and financial recovery of the award from the nominating Division or Department
- *T32 Applicant's Only* the letter of support from the Division Chief must include an attestation of 75% protected research time, scheduling to accommodate master's coursework, required short courses and seminars, and biannual site visits.

Supervisor/Primary Research Mentor

Training should be pursued in the wet or dry laboratories of mentor(s) who have or have had significant extramural funding for outstanding research programs and a track record for training researchers. If the supervisor is an Assistant Professor, then a more senior research mentor must be integrally and intimately involved in the fellow's research program. The supervisor/primary research mentor must have a history of being the primary supervisor of successful research trainees.

A Mentor Support Form is *required* from the *Primary Research Mentor* for all applicants. The *Primary Research Mentor* must be a Member of the MCHRI; a membership form is available here.

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.

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Letters of Support

- Letters of support are required from all listed nonprimary 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 *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 Budget Worksheet detailing all current and potential other sources of funding for this study.

Clinical Trainee (MD) Support Budget Worksheet.

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.

IRB Approval

It is <u>strongly encouraged</u> that you submit your IRB application <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 approval letter, it must be attached with the application. If approved for funding, the award cannot commence (fund transfer) without the approved IRB. Should there be a reason you will not have IRB approval by the award start date of 7/1/24, please email <u>mchri_admin@stanford.edu</u> to request a waiver and include a justification in your request.

For more information, please see: http://humansubjects.stanford.edu/

AWARD

The MCHRI Clinical (MD) Trainee Award:

- Provides <u>up to</u> 100% salary support plus fringe for up to two years (non-competitive renewal for year 2)
- Supports PGY5 and PGY6 (2nd and 3rd years) of fellowship only.
- Shall be used for the fellows' remuneration and benefits (at the level determined appropriate for their specialty)

Review Timeline

- One grant cycle is offered annually in the spring.
- Formal award letters will be issued in June. Award will have a start date of July 1.

Documentation of External Application

Renewal funding is contingent upon documentation that the applicant has applied to a competitive external agency (outside of Stanford) by May 15 in the first year of the award to support their research fellowship or residency, as appropriate with their discipline support their research fellowship, or residency, as appropriate with the discipline³

Determination of Funding Level

If the applicant is successful in obtaining external funding for his/her salary for part of year 1 or the renewal year, s/he/they must immediately notify the MCHRI. *In such a situation, the MCHRI award will be reduced by a comparable amount.* External funding is defined as any non-Stanford, competitive funding mechanism that is applied for directly by the awardee. E.g., NIH F32 meets the criteria. A T32 does not meet the criteria.

However, if the applicant is successful in obtaining external salary funding, an incentive 'bonus' of <u>up to</u> \$10,000 will be awarded to the fellow, to be used for any purpose at the discretion of the mentor, except for the purchase of computers. The purchase of computer software must be justified. Each awarded fellow may only receive the incentive bonus once during their fellowship. The amount of the incentive 'bonus' will be awarded as follows:

| External Award (Salary) | MCHRI Incentive Bonus |
|---------------------------|--------------------------|
| ≥ \$35,000 | \$10,000 |
| ≥ \$20,000 and < \$35,000 | \$5,000 |
| ≥ \$5,000 and < \$20,000 | \$2,500 |
| ≥ \$0 and < \$5,000 | \$0 |

The funding level for MCHRI Research Fellows requesting a year 2 Non-Competitive Renewal will depend on each fellow's external funding situation during year 2 as outlined above. Non-competitive renewal is only available to MCHRI fellows in their second year of training (PGY5). Funding level is contingent upon availability of funds.

SCORING AND REVIEW CRITERIA

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

 Significance. Does this study address an important [child¹ health] problem? If the aims are achieved, how will scientific knowledge or clinical practice be

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³ For example, the training of a pediatric surgeon.

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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 the MCHRI Scientific Review Committee.

Reviewer Comments

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

AWARDEE RESPONSIBILITIES

Term of Appointment

All appointments are term limited for a single term of <u>up</u> <u>to</u> 2 years. Should there be a change in the awardee's role that significantly alters their ability to carry out their responsibilities as a MCHRI Fellow 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 and MCHRI will resume award payment upon awardee's return.

Progress Reports

MCHRI Research Fellows must submit an Annual Progress Report for each year funded by the MCHRI.

The MCHRI Research Fellow recipient:

- Has the responsibility for timely submission of a Progress Report by May 15 in the first year of the award wherein progress is outlined.
- Must provide timely update on funding status from external and/or internal sources.
- Has the responsibility for submission of Annual Progress Reports for 3 years <u>after</u> the end of the MCHRI fellowship funding including updated peerreviewed publications, employment, and competitive funding (federal or national non-profit foundations).
- 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.

CONTACT

MCHRI Administration: mchri admin@stanford.edu or 650-724-0279

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