

STANFORD MATERNAL AND CHILD HEALTH RESEARCH INSTITUTE

Uytengsu-Hamilton 22q11 Neuropsychiatry Research Program

Stanford Applications – Full Proposal Policy

ELIGIBILITY

Research must be related to the specific mission of the Stanford MCHRI Uytengsu-Hamilton 22q11 Neuropsychiatry Research Program which is to improve the neurocognitive outcomes and behavioral symptoms of 22q11.2 Deletion Syndrome (22q11.2DS). The program specifically seeks to identify strategies with potential for patient impact within 5 years, however short-term and long-term therapeutic approaches and basic science proposals will be considered for funding if the scientific rationale is compelling.

This program will support a wide range of scientific approaches in the following areas:

- I. Basic and clinical translational research, including but not limited to neuroscience, genetics and genomics, psychiatry, neuroimmunology, metabolism, and novel therapeutics (up to a maximum of \$150K/year, requests at a lower level of funding are welcome)
- II. Data science, bioinformatics and computational methodologies utilizing existing data (up to a maximum of \$100K/year, requests at a lower level of funding are welcome)

Eligible applicants must be Stanford faculty holding Clinician Educator (CE), University Tenure Line (UTL), Research (NTL-Research), or Medical Center line (MCL) positions for the duration of the award.

An interdisciplinary approach is strongly encouraged for this initiative where at least two of the lead investigators bring expertise from different disciplines. Collaborations between basic and physician scientists are particularly encouraged. Applications may include co-investigators from other research organizations. Single-PI applications will be considered if the scientific rationale is compelling.

Applicants may only submit one application as Principal Investigator. Applicants may be included as co-investigator on more than one application.

Applicants not funded in previous funding cycles may resubmit proposals. Applicants are encouraged to address feedback from peer review in the revised proposals.

Current or previous award holders of the Stanford MCHRI 22q11.2DS Neuropsychiatry Research Program are eligible to apply, if the end date of their current award falls before March 1, 2022. Applicants who currently hold or have previously received funding from this program should clearly describe the outputs of previous funding.

This program will fund innovative projects in the following categories:

- **Category A:** Research at Stanford University (up to 4 awards)
- **Category B:** Research external to Stanford University (up to 2 awards)

APPLICATION

The applicant must submit the following as a single PDF document:

- Cover page (using format provided)
- Lay Summary
- Research Proposal
- Research Team
- IRB Approval documentation

Lay Summary:

Outline the importance and clinical need for the proposed research, using plain language aimed at a general audience. Describe how the proposed research would generate new knowledge of the neuropsychiatric manifestations of 22q11.2DS and the potential therapeutic impact or benefit to people with 22q11.2DS in the short or long term. The lay summary should not exceed 250 words.

Research Proposal:

- Concise description of the specific aims and research strategy, including significance, innovation, preliminary studies (if available), experimental approach, research team, and project timeline.
- Proposals should include a plan for statistical analyses and a brief description of sample size and statistical power calculations.
- Proposals should clearly articulate the relevance to 22q11.2DS and potential for patient impact.
- The proposal should be a maximum six pages text, Arial 11pt or similar, not including references, and no more than five additional pages of attachments or appendices.

Research Team:

For all members of the proposal submit:

- A NIH Biosketch (including Personal Statement) from the applicant, each co-investigator and collaborator.

IRB Approval (Approved Before Application):

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 be approved without the approved protocols. For more information, please see: <http://humansubjects.stanford.edu/>

Budget Worksheet:

The applicant must submit a MCHRI Budget Worksheet (using format provided), including all current and potential other sources of funding for this study.

Video Presentation:

- The applicant must submit a video presentation providing a summary of the research proposal and study design, including a lay summary. The recording should be submitted in mp4 format, and can be made using e.g. Powerpoint record slide show function, or a Zoom meeting recording. The recording should be a maximum of 5 minutes in duration.

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.

MCHRI Resources

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. Contact MCHRI Administration to request coordinator services.

Patient Oriented Research at SCH

Studies involving patients at Stanford Children's Health (SCH) must contact the SCH Clinical Research Support Office *early in the study design phase* 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 SCH without CRSO consultation will not be reviewed or may be asked to resubmit in the next cycle.

MCHRI Drug & Device Development (D3) 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.

AWARD

Up to (I) \$150,000 / year or (II) \$100,000 / year for up to two years. Unexpended funds will be returned to the MCHRI after the performance period (see No-Cost Extensions below).

Award may be used for:

- Research personnel
- PI salary

- Computer software (must be justified), supplies or other materials/ services relevant to the research project
- Travel, symposia, or seminars which are an integral part of the proposal

Award may NOT be used for:

- Other travel, conference fees, tuition, or 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
- Any other indirect research costs including subrecipient F&A costs

NO-COST EXTENSIONS

Requests must be submitted at least sixty (60) days prior to the end date on the award letter. Requests are considered on a case-by-case basis. Not all requests are approved. Only one extension request is permitted per project.

SELECTION PROCESS AND ASSESSMENT CRITERIA

Proposals are reviewed by the Stanford MCHRI Uytengsu-Hamilton 22q11 Neuropsychiatry Research Program Scientific Advisory Board. Current SAB membership is available on the MCHRI website. Assessments will be based on the NIH Investigator-Initiated Review Criteria – significance, innovation, approach, research environment and investigator team – and the relevance and potential impact of the research on the neuropsychiatric outcomes of 22q11.2DS.

AWARDEE RESPONSIBILITIES

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

- Successful applicants will become members of the Stanford MCHRI Uytengsu-Hamilton 22q11 Neuropsychiatry Research network. The members are expected to attend regular meetings and demonstrate scholarly stewardship within the program through scientific collaboration and intellectual contribution to the programs shared mission.
- Member of MCHRI, keep Stanford Medicine Profile (formerly-CAP) updated, and utilize “Permit PubMed Import” feature.
- Award recipient and their division/department are responsible for coordinating the transfer of funds to sub-recipients, if applicable.
- Submit reports in a timely manner, including an annual Progress and Financial Report, and a Final Progress and Financial 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 research funding resulting from this award.
- Present the results of their research when asked.
- Acknowledge the research support of the Stanford Maternal and Child Health Research Institute and Stanford MCHRI Uytengsu-Hamilton 22q11 Neuropsychiatry Research Program in all publications, abstracts, presentations, press releases, and inventions resulting from this award as follows:

“The project described in this publication was supported by the Stanford Maternal and Child Health Research Institute Uytengsu-Hamilton 22Q11 Neuropsychiatry Research Program.”

MCHRI award recipients who have not acknowledged the Stanford MCHRI Uytengsu-Hamilton 22q11 Neuropsychiatry Research Program are not eligible for future awards sponsored by the MCHRI.

TERM OF AWARD

All awardees are limited to a single award of up to 2 years. Should there be a change in the awardee’s role that significantly alters their ability to carry out 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

Prior to submission, applicants are welcome to contact the Program Director to discuss their research proposal, feedback from the Scientific Advisory Board, eligibility queries, or for assistance with coordination and identification of MCHRI and Stanford resources.

Rachael Panizzo PhD, Program Director:
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