Technical Assistance Webinar for Research Networks To Promote Mechanistic Studies of Music-Based Interventions (RFA-AT-23-009)
November 30, 2022

UPDATE: We terminated RFA-AT-23-006 due to a problem with the review criteria. Unfortunately, there was a technical glitch with the RFA reissued on December 8 (RFA-AT-23-008). Thus, we also terminated that funding opportunity and reissued a new RFA (RFA-AT-23-009) on December 16, 2022. There is a NEW application due date of **January 17, 2023**. Beyond this, there were no substantive changes in the scientific content and review criteria. **Please use RFA-AT-23-009 to apply.**

Purpose of the Webinar

On Wednesday, November 30, 2022, the National Center for Complementary and Integrative Health (NCCIH) and National Institute on Aging (NIA) of the National Institutes of Health (NIH) hosted a technical assistance webinar to share information about the Research Network(s) To Promote Mechanistic Studies of Music-Based Interventions U24 funding opportunity.

Webinar Speakers and Panelists

- Wen Chen, Ph.D., Branch Chief, Basic and Mechanistic Research Branch, Division of Extramural Research (DER), NCCIH
- Coryse St. Hillaire-Clarke, Ph.D., Program Director, Sensory/Motor Disorders of Aging Program, Division of Neuroscience, NIA
- Shiyong Huang, Ph.D., Scientific Review Officer, Division of Extramural Activities, NCCIH
- Anita McRae-Williams, M.A., Outreach Communications Program Manager, DER, NCCIH (Webinar Moderator)

Ms. McRae-Williams opened the webinar, explaining that it would be an hour long, with the first half devoted to presentations by program and review staff and the second half devoted to answering questions from webinar participants. She explained that Dr. Chen is the NCCIH scientific contact for this funding opportunity announcement (FOA) and Dr. St. Hillaire-Clarke is the NIA contact.

Background and Rationale for the Funding Opportunity

Dr. Chen explained that NIH's journey into research on music-based interventions (MBIs) began when Dr. Francis Collins, former director of NCCIH, and soprano Renée Fleming sang together at a social event and started to explore the concept of music as medicine. Continued interest in this topic led to "Music & the Brain: Research Across the Lifespan," an exciting NIH workshop, in January 2017. The workshop involved a panel of 25 researchers from the United States, Canada, and Europe, with expertise ranging from the basic neuroscience of music to clinical trials and music therapy. Representatives from the John F. Kennedy Center for the Performing Arts, the National

Endowment for the Arts, and music therapy professional and advocacy groups also participated in the workshop.

The workshop organizers and some of the speakers then wrote a [review article on music and the brain](#), which was published in the journal *Neuron*. The review included four recommendations for future activities to support research on music and health. This FOA focuses on the fourth recommendation, which involves building capacity and infrastructure, particularly through multidisciplinary networks.

Structure of the Funding Opportunity

NCCIH and NIA have issued this FOA, using the U24 cooperative agreement funding mechanism, to support three research networks. All three will focus on aspects of MBIs, with two networks focusing on pain-related outcomes and one on Alzheimer's disease and Alzheimer's disease related dementias (AD/ADRD).

This is a unique type of NIH funding opportunity, very different from an FOA for research projects. Unlike research-focused initiatives, research networks support broader activities and function in a different way. These research networks will support three types of activities:

- Collaborations, such as meetings, workshops, conferences, and exchanges
- Pilot research projects
- Sharing of information, for example through publications or dissemination and outreach activities

Each network must choose one to three scientific topic areas to focus on, within these three categories:

- **Music interventions** (e.g., definition and differentiation of different types of MBIs, identification or definition of various active components of music or MBIs)
- **Mechanisms and biomarkers** (e.g., exploration of innovative neural mechanistic hypotheses of the systems involved in the therapeutic effect of music, examination of nonneural physiological systems and novel measures relevant to music or MBIs, discovery of biomarkers for MBIs in the context of pain or AD/ADRD)
- **Technologies, tools, and models** (e.g., development of novel technologies to measure the impact of MBIs or monitor responses to them, development and testing of animal models to study mechanisms and biomarkers in the context of pain or AD/ADRD)

The Research Strategy Section

The required components that must be included in the Research Strategy section of a U24 application and summarized in the Specific Aims are different from the information that would be included in an application for a research grant such as an R01 or R21.

It is particularly important to include sufficient background information. Why is it important to create your proposed research network? What gaps and opportunities of

mechanistic research will your network address?

In the Innovation section, it is important to highlight any methodological and organizational innovations of your proposed research network. Theoretical innovations are not a focus here.

The Approaches section should include:

- An overview of the scientific framework, organizational structure, and leadership team of the proposed network
- Methods to create and sustain the network
- Methods to identify and support small-scale 1-year pilot projects, including a formal plan to solicit, review, select/prioritize, and support the projects
- Methods to promote dissemination, training, and research
- A summary of network milestones, a timeline, and a network evaluation plan

You may also add other information to show how your application is unique or competitive, and you might consider adding potential caveats and backup strategies for your proposed approaches.

Responsiveness Criteria

For an application to be considered responsive to this FOA, it must do the following:

- Include proposals for all the required network activities, including collaborations, pilot projects, dissemination, milestones, and progress evaluations.
- Address at least one of the three high-priority research areas (MBIs, mechanisms/biomarkers, or technologies/tools/models).
- Focus on one (and only one) of the two health conditions (pain or AD/ADRD).
- Span multiple disciplines.
- Provide a formal plan for pilot projects, including examples of the focus of potential pilot projects. **However, describing an actual pilot project is not encouraged.**
- Propose novel activities that are not feasible with existing resources and funding mechanisms for research on MBIs.

Applications that propose any of the following will be considered nonresponsive:

- Clinical trials of interventions other than MBIs
- Pilot project solicitations that would support trials of MBIs with clinical endpoints
- Traditional investigator-initiated research projects (These are best supported by the R01, R21, R61/R33, or P01 activity codes.)
- Core services to supplement the budgets of existing R01-type projects
- Groups of investigators at the same institution who would normally interact and collaborate
- Scientific meetings only (Proposals of this type should use PA-18-648 instead.)
- Support for pre- and postdoctoral research training programs (Proposals of this type should use PA-20-142 instead.)

Support for research education activities only (Proposals of this type should use the R25 funding mechanism instead.)

Application budgets are limited to $300,000 in direct costs per year, and the maximum project period is 5 years.

NCCIH will support two awards focusing on pain ($5 million over 5 years, including indirect costs), and NIA will support one award focusing on AD/ADRD ($2.5 million over 5 years, including indirect costs).

Registrants for this webinar will be sent a list of experts who are willing to share their names, contact information, and expertise.

Change in RFA Number

The number currently assigned to this request for applications (RFA) is incorrect. The new RFA number is RFA-AT-23-008. Everyone who registered for this webinar will be sent this new RFA number with a brief explanation on December 9, 2022. The change in RFA number will not affect the application process. Potential applicants may submit their letters of intent without the new RFA number.

Review Perspective

Dr. Huang explained key factors that impact the review of applications for this funding opportunity:

- **Responsiveness.** Applicants should check the Responsiveness Criteria in the FOA. Look for "must", "need," and "required" when reading through the Scope and Responsiveness Criteria. **Applications that are not responsive will not move forward to review.**
- **Compliance.**
    - Applications must comply with the budget limit ($300,000 in direct costs per year).
    - The scope of the proposed project should determine the project period (maximum 5 years).
    - Foreign institutions are not eligible to apply, but foreign components are allowed.
    - Page limitations: 1 page for Specific Aims, 12 pages for Research Strategy.
    - Requirements include collaboration, pilot projects, a dissemination plan, milestones, and a resources and data sharing plan.
    - Applications must comply with all instructions for allowable appendix material as described in the SF424 (R&R) Application Guide.
    - Post-submission materials, such as news of a paper accepted for publication, must be submitted by 30 calendar days before the peer review meeting. Preliminary data may be included in the post-submission

materials. Information accidentally left out of the application cannot be submitted as post-submission material.

- **Review Criteria.** Applications will be scored according to the five standard review criteria (Significance, Investigator[s], Innovation, Approach, and Environment). Additional review criteria, including the study timeline (milestones), protections for human subjects, inclusion plans, vertebrate animals, biohazards, and a resources and data sharing plan, will also be factored into the overall impact score. Additional language has been added to the standard review criteria for this FOA. **Please make sure you read and take into consideration the review criteria.** Reviewers will be asked to address the same areas that applicants are asked to address.

Review of applications will be conducted in a special emphasis panel at NCCIH. Reviewers will be selected based on specific areas of expertise in the target areas of the RFA and the science proposed in the applications.

Dr. Huang advised applicants to keep in mind how their applications would be impactful considering the goals of this funding opportunity.

Important Dates

Letters of intent are optional but very much appreciated. They are due **December 10, 2022.** They should be addressed to Dr. Martina Schmidt at SchmidMa@mail.nih.gov and should include the following bullets:

- Descriptive title of the proposed activity
- Name(s), address(es), and telephone number(s) of the program directors (PDs)/principal investigators (PIs)
- Names of other key personnel
- Participating institution(s)
- Title of this funding opportunity

The application due date is **January 10, 2023.** Late submission will be considered.

The review meeting will be held in **April 2023,** and the earliest start date is **August 2023.**

Questions and Answers

Q1: An attendee who is a data scientist and Tibetan healer asked to be connected with experts in AD/ADRD.

A1: Dr. St. Hillaire-Clarke recommended that this individual visit the NIA website and look up information on the AD research centers that NIA funds. The website has a great deal of information about the directors of those centers, including neurologists whom the questioner could connect with.

Q2: Can you provide more detail on the ideal composition of networks, and do you envision interdisciplinary teams within one institution or regional networks across institutions?

A2: Dr. St. Hillaire-Clarke explained that if groups already have a history of working together without new partnerships, especially within the same institution, this will likely not be viewed favorably by reviewers. Dr. Chen added that an application from investigators who already work together at the same institution could be considered nonresponsive. One of the purposes of research networks is to bring investigators together. NCCIH and NIA are encouraging applicants to reach out to each other to make new connections. Only three networks will be funded.

Q3: With the requirement to be multidisciplinary, what are the expectations for documenting existing collaborations, usually done with publications for research grants?

A3: Dr. Chen explained that it is not necessary to have documentation of existing collaborations. Applicants can plan to work with people with whom they have not collaborated before. Documentation of expertise is important, but having existing collaborations is not essential for this RFA.

Q4: Do we need to include in the network organizations that are already working in music therapy, or can we establish new ones?

A4: Dr. Chen said that either approach would be possible, and that representatives of existing music therapy professional organizations could be included in a network. Applicants could build on existing associations or create new ones.

Q5: How is including international partners outside of the U.S. viewed?

A5: Dr. Chen explained that foreign components are allowed, so you certainly can have foreign collaborators. Applications from foreign institutions, with the contact PI from the foreign institution, are not allowed, but a foreign co-investigator would be acceptable.

Q6: Can I submit two U24s, one for pain and the other for AD/ADRD?

A6: Dr. Chen said yes, but she cautioned that applicants may not submit a single U24 that includes both conditions. Dr. St. Hillaire-Clarke added that applications that are highly overlapping cannot be reviewed at the same time; one will be withdrawn.

Q7: Is there a recommended number of institutions or PIs to include in a network?

A7: Dr. Chen said that there is no recommended number, although the number would be influenced by the budget. Because of the requirement for a multidisciplinary team, at least two different institutions and two PIs would be expected.

Q8: Given the change in RFA number, should we wait to start the application in ASSIST, or will that not matter? [ASSIST stands for Application Submission System & Interface for Submission Tracking.]

A8: Dr. Huang said that applicants should wait to submit their applications in ASSIST until we have the new RFA number. Dr. Chen pointed out that applications cannot be submitted until 30 days before the submission deadline anyway, and by that time the new RFA number should be available. However, applicants can start to prepare the content of their applications at any time. The issue with the RFA number was unexpected and came up only recently. NIH needs some time to resolve it, but the new number is likely to be available by December 10.

Q9: Is there a minimum number of pilot projects required?

A9: Dr. Chen said that there is no minimum number, but there is a budget requirement for pilot projects. You are expected to spend at least a third to half of your budget supporting pilot projects. A typical pilot project would involve about $50,000 in direct costs for 1 year. That information can be used as a benchmark for how many pilot projects you would want to support in a year.

Q10: Is there a certain format for the letter of intent?

A10: Dr. Huang said that this information is provided in the RFA section IV. The letter should include the title of the proposed activity; name, address, and phone number of the PD/PI; names of key personnel; names of participating institutions; and title of the funding opportunity. The email should be sent to Dr. Martina Schmidt. Dr. Chen added that applicants do not need to include specific aims in their letters of intent, and that information in the letter—including the title of the project or the names of PIs—can be changed before the application is submitted.

Q11: Can you provide information on the types of dementias included in the RFA?

A11: Applicants may focus on AD and/or any of the ADRDs. Dr. St. Hillaire-Clarke explained that the national plan to address AD defines ADRDs to include dementia due to:

1. Frontotemporal dementia (FTD), primary progressive aphasia (PPA), progressive supranuclear palsy (PSP), corticobasal degeneration (CBD), and Pick's disease
2. Lewy body dementia (LBD) including dementia with Lewy bodies (DLB), and Parkinson's disease dementia (PDD)
3. Vascular dementia including vascular dementia, vascular cognitive impairment (VCI), multi-infarct dementia, post-stroke dementia, and vascular brain injury
4. Mixed pathologies
5. Down syndrome

Q12: If the focus of someone's research is not in the area of pain or AD/ADRD, can they still apply to this RFA?

A12: Dr. St. Hillaire-Clarke said that because the RFA is focused on MBIs for these conditions, other conditions are not within its scope. However, it is certainly possible that a research team could include collaborators with relevant knowledge and skills in other areas.

Q13: Will recipients of network awards be able to apply for administrative supplements in subsequent years?

A13: This depends on whether the supplement call includes U24s. Supplement calls typically have a notice that specifies which activity codes are eligible.

Q14: I understand that this is not a training grant, but is it permissible to include a doctoral student in the budget?

A14: It would be all right for the student to help with the proposed network activities. But this is not a grant for a research project, and it would not be a good idea to include the student's project as a pilot project.

Q15: What was the rationale for NIH's choice of AD/ADRD and pain as the conditions to study?

A15: The rationale was based on NCCIH's and NIA's priorities. AD/ADRD is a high priority for NIA, and pain is a high priority for NCCIH. You can learn more from NIA's and NCCIH's strategic plans.

Q16: If you have several subcontracts, how are indirect costs calculated?

A16: Dr. Chen said it is based on the subcontract agency's indirect rate. Where the indirect costs come from depends on how you call for your pilot projects. The subcontract might have your own indirect rate, but otherwise indirect rates are set by negotiation between the institution and the Government.

Q17: If a PI is a member of an existing research network that does not focus on music-based research, would an application that proposes to expand the existing network to MBIs be responsive?

A17: Both Dr. Chen and Dr. St. Hillaire-Clarke expressed reservations about this idea. The goal of the RFA is to build MBI networks, and this approach would not do that. Also, unless the existing network had the same design and requirements as those called for in this RFA, it probably would not work.

Q18: Can you clarify if a pain-related application can focus on a specific population such as patients with critical illnesses?

A18: Dr. Chen said that this would be allowed, but the application could be competing with others that are more broadly focused. The RFA does not specify the type of pain.

Dr. Chen suggested that NCCIH's and NIA's strategic plans can help applicants understand their priorities. Alignment with the priorities affects the chances of obtaining funding.

Q19: Applications must describe how the proposed activity will engage with other relevant activities at participating institutions. Can you give examples of how networks might engage?

A19: Dr. Chen explained that, for example, if you are proposing workshop activities, you may want to describe how they would influence your dissemination goals or pilot project selection process. The different activities of the network should be aligned for common goals, rather than being isolated from one another.

Q20: Is it a requirement to have a music-based investigator on the proposal?

A20: Someone on the team needs to understand music or MBIs. Without such a team member, an application may not fare well in review.

Q21: Are international collaborations acceptable?

A21: Dr. Huang said that foreign institutions are not eligible to apply, but foreign components are allowed. The NIH Grants Policy Statement defines foreign components as follows:

> "The performance of any significant scientific element or segment of a project outside of the United States, either by the recipient or by a researcher employed by a foreign organization, whether grant funds are expended. Activities that would meet this definition include, but are not limited to, (1) the involvement of human subjects or animals, (2) extensive foreign travel by recipient project staff for the purpose of data collection, surveying, sampling, and similar activities, or (3) any activity of the recipient that may have an impact on U.S. foreign policy through involvement in the affairs or environment of a foreign country. Examples of other grant-related activities that may be significant are
> - Collaborations with investigators at a foreign site anticipated to result in co-authorship.
> - Use of facilities or instrumentation at a foreign site; or
> - Receipt of financial support or resources from a foreign entity.
>
> Foreign travel for consultation is not considered a foreign component."

Dr. Chen explained that foreign personnel working for U.S. institutions may apply if they are permitted to apply for U.S. grants.

Q22: Will the webinar be available to watch again?

A22: Ms. McRae-Williams said that it would not be available, but a written summary and the speaker slides will be sent to all registrants.

Q23: Is the purpose of the network to bring together entities that have not worked together previously to ensure high risk and high return?

A23: Dr. Chen said that this is not the stated purpose. The purpose is to promote networking and collaborations. There is no requirement regarding whether entities in the network have or have not worked together before. However, the network cannot consist only of people from one institution who normally work together. Dr. St. Hillaire-Clarke explained that different people and perspectives are desired. Innovation is less likely with a group that already works together. Dr. Chen noted that the networks should expand after funding because of the pilot projects and other activities. Applications should describe the network's membership mechanism, that is, how the network will be built as time goes on.

Q24: Should a sample pilot project be included in the proposal?

A24: No. You should describe the focus or topic areas of the projects that will be solicited but including a sample project is not encouraged.

Q25: Do Co-PI and MPI refer to the same thing?

A25: Dr. St. Hillaire-Clarke said that the terms co-PI and multiple PI (MPI) are often used interchangeably, but they are slightly different. Dr. Huang said usually only co-investigators and MPIs, not co-PIs, are used by NIH. This page clarifies the different roles.

Q26: What's the difference between a PI and a project lead?

A26: Dr. Chen explained that there would be no project lead because no projects will be proposed.

Q27: Will this RFA be renewed?

A27: Dr. Chen said there are no plans right now to renew it.

Q28: Should the PI have experience in both building networks and implementing MBIs or is type of experience alone sufficient?

A28: Dr. Chen explained that because networks are not usual, experience in building networks would not be expected. But the application should be written to show that you have the capability to do this. Dr. St. Hillaire-Clarke said that a history of collaborations would help.

Q29: Do we need to have the collaborating institutions/elements finalized for the letter of intent?

A29: Dr. Chen said it need not be final, but you should provide some information. Dr. Huang said that one purpose of the letter of intent is to help NIH prepare for review. If

NIH knows that an individual is applying to this funding opportunity, that person will not be invited to be a reviewer.

Q30: Is it feasible to include networks for different types of musical rhythms?

A30: You could have a network focused on musical rhythm, but it is important to remember that the networks must involve one of the clinical conditions—pain or AD/ADRD.

Q31: Would a company that's studying how vital signs can be used to recommend playlists for people with AD be eligible?

A31: The questioner was asked to email Dr. St. Hillaire-Clarke about this topic.

Q32: A question about clarification of mechanisms of action was asked at this point, but the panelists did not understand what type of information was needed. The questioner may want to contact one of the panelists directly.

Q33: Is dance considered an MBI?

A33: Dr. Chen said yes, it is one form of an MBI, if it contains musical elements.

Q34: For ADRD, is affiliation with an NIA-funded Alzheimer's Disease Research Center (ADRC) required, preferred, or not a huge factor?

A34: Dr. St. Hillaire-Clarke said it is not required, but it may be a good idea to reach out to an ADRC.

Q35: Could solicitations for pilot projects ask that indirect costs not be included?

A35: Dr. Chen said that this is up to the PI's institution.

Q36: Must the required dissemination include publication in a scientific journal?

A36: Dr. Chen said that this is not required. However, the dissemination plan will be evaluated.

Q37: Can new curricula for music-based therapies be considered a tool?

A37: Dr. Chen said no, this funding opportunity is not for curriculum development.

Q38: For soliciting pilot projects, can we have an internal person act as a program officer to facilitate review?

A38: Dr. Chen said no. In the RFA, there is a description of the process for soliciting pilot projects. Typically, evaluation is performed by a committee rather than an individual.

Q39: Are intergenerational projects acceptable?

A39: Dr. Chen said that projects should not be proposed. Only topic areas should be proposed.

Ms. McRae-Williams recommended that attendees with questions about their individual applications should follow up with the program directors—Dr. Chen at NCCIH for proposals involving pain and Dr. St. Hillaire-Clarke at NIA for proposals involving AD/ADRD. Ms. McRae-Williams then closed the webinar.