REsearch Across Complementary and Integrative Health Institutions (REACH) Virtual Resource Centers (U24 Clinical Trial Not Allowed) Technical Assistance Webinar (RFA-AT-24-009)

Purpose of the Webinar

On Tuesday, June 18, 2024, the National Center for Complementary and Integrative Health (NCCIH) hosted a technical assistance webinar to share information about the reissued notice of funding opportunity (NOFO) RFA-AT-24-009: REsearch Across Complementary and Integrative Health Institutions (REACH) Virtual Resource Centers (U24 Clinical Trial Not Allowed) and answer questions from potential applicants. This was followed by a teaming activity to give potential applicants from resource-intensive institutions an opportunity to network with potential partners from complementary and integrative health clinical institutions. This summary covers only the technical assistance webinar.

Webinar Speakers

- Lanay Mudd, Ph.D., Deputy Branch Chief, Clinical Research in Complementary and Integrative Health Branch, Division of Extramural Research, NCCIH
- Marta Hamity, Ph.D., Scientific Review Officer, Office of Scientific Review, NCCIH
- Anita McRae-Williams, M.A., Outreach Communications Program Manager, Division of Extramural Research, NCCIH (webinar moderator)

Ms. McRae-Williams welcomed the webinar participants. She explained that the technical assistance webinar would be an hour long and would include presentations by program and review staff, as well as time for answering questions from webinar participants. After the technical assistance webinar, there would be a teaming opportunity available. She noted that participants would receive the speakers' slides and a brief survey by email after the webinar ends, followed by a detailed written summary of the webinar within about 8 days. Attendance at this webinar was optional and not a requirement for application submission.

Preparing for the Teaming Opportunity

Dr. Mudd explained that partnerships between research-intensive and clinical complementary and integrative health institutions are a key feature of this request for applications (RFA). To facilitate the formation of partnerships, NCCIH is providing two opportunities for institutions to connect:

- By meeting in breakout rooms during the teaming opportunity immediately after this webinar
- By sharing names and contact information of webinar registrants

Participants who do not want their contact information shared with other attendees should notify Whitney Ratliff at Whitney.Ratliff@nih.gov by noon on Thursday, June 20.

Purpose of This RFA

Dr. Mudd explained that the NCCIH strategic plan has three primary research objectives and two cross-cutting objectives. This RFA focuses on one of the cross-cutting objectives: "Enhance the complementary and integrative health research workforce."

The RFA also responds to a report of an NCCIH advisory council working group. The working group was convened to address research training and career development for clinician scientists in complementary and integrative health and address needs and gaps. The working group report pointed out roadblocks to clinician-scientist careers and recommended developing innovative approaches to overcome them. These approaches include supporting research training for clinicians with complementary and integrative health degrees, developing programs to support the host environments at institutions involved in research training in complementary and integrative health, and incentivizing institutions to reward teams that include both scientists and clinicians. This RFA addresses some of the working group's recommendations, focusing on institutional-level partnerships.

Rationale for the REACH Resource Centers

Research-intensive institutions and complementary and integrative health clinical institutions each have strengths and weaknesses.

- Research-intensive institutions offer a strong research infrastructure, grantsmanship courses and support, research training, interdisciplinary networks, and principal investigators (PIs) with a history of National Institutes of Health (NIH) funding. However, they may lack a strong presence of clinician scientists trained in complementary and integrative health disciplines.
- Complementary and integrative health clinical institutions have faculty with clinical training to inform research questions and offer a strong clinical training environment to contribute to knowledge generation. However, they may lack the research infrastructure and environment to support the careers of clinician scientists.

The REACH Resource Centers will combine the strengths of the two types of institutions.

The goals of the REACH Resource Centers are to:

- Improve the quality and quantity of Federal research grant applications submitted by clinician-scientist faculty at complementary and integrative health clinical institutions.
- Aid the formation of multi- and interdisciplinary partnerships across partnering institutions.
- Enhance the research environment at partnering clinical institutions to expose more students to research.
- Support a pipeline for clinician scientists to gain expertise in clinical science and pursue research careers.

The REACH Resource Centers will be virtual scientific hubs located at research-intensive institutions. They will support both research activities and research training at partnering complementary and integrative health clinical institutions. The resources that are provided should support research with human subjects that is aligned with NCCIH's strategic priorities for health promotion and restoration, resilience, disease prevention, symptom management, and/or whole person health.

Application Requirements

Dr. Mudd highlighted several essential elements that must be included in applications submitted in response to this NOFO:

- **An institutional letter of support from the applicant's own institution** (the resource-intensive institution) detailing its qualifications for providing REACH resources, including:
    - A strong concentration of NIH-funded investigators with expertise in complementary and integrative health research
    - A track record of collaboration among participating faculty at the REACH Center
    - The ability to provide expertise for all proposed resources, including coordinated mentoring for complementary and integrative health research
    - (Preferred but not required) Institutional experience partnering with less resourced institutions to build research capability
- **Virtual resources to support human subjects research** (which could include epidemiological and observational studies as well as clinical trials) in **all** of these five categories:
    - Administrative support (e.g., assistance with budget development, support for subaward and contract negotiations)
    - Research support (e.g., access to statistical expertise, computational software, central institutional review board [IRB] services)
    - Grantsmanship (e.g., assistance with identifying appropriate funding opportunities, critical review of proposals)
    - Mentorship and training (e.g., formal and informal mentorship programs, individual development plans)
    - Team building (e.g., matchmaking services to fill gaps in expertise, training in team science methods)
- **A process to support small-scale pilot projects** for scholars from partnering clinical institutions.
    - Applicants must describe a plan to solicit, review, and select projects for funding and to evaluate progress and outcomes.
    - Pilot projects should have the potential to inform subsequent NIH applications aligned with NCCIH priorities.
    - Descriptions of actual pilot projects should **not** be included in the REACH Center application.
- **Three letters of support from partnering accredited U.S. domestic complementary and integrative health clinical institutions,** such as schools of acupuncture, chiropractic, osteopathy (if manual manipulation is included in the core curriculum), naturopathy, physical therapy, and music and art therapy.
    - A breadth of clinical disciplines must be included.
    - Partnering institutions must:
        - Demonstrate willingness to engage with the REACH Center.
        - Commit in-kind support to provide at least 20 percent protected time for faculty to participate in REACH.

    - The application must provide plans for expanding to additional partnerships over time.
- **A Plan for Enhancing Diverse Perspectives (PEDP)**
    - This is a two-page summary of strategies to advance the scientific and technical merit of the proposed project through expanded inclusivity.
    - The PEDP will be assessed as part of peer review and considered in funding decisions.

Application budgets may not exceed $850,000 per year in direct costs and should reflect the actual needs of the proposed project. Up to $100,000 per year may be budgeted for the pilot study program. The maximum project period is 5 years. NCCIH intends to commit $2.75 million in FY 2025 to support up to two awards.

The Cooperative Agreement Support Mechanism

The funding mechanism that will be used for the REACH Centers is a cooperative agreement mechanism. This mechanism is used when there will be substantial Federal scientific or programmatic involvement in a project. After the award is made, a project scientist from NIH will be assigned to participate in the project. The Cooperative Agreement Terms of Award near the end of the NOFO explain the roles and responsibilities of the PI and NIH staff.

Review Perspective

Dr. Hamity provided details on factors that impact the review of applications under this NOFO. She cautioned that applications that are incomplete, noncompliant, or nonresponsive to the NOFO may not be accepted for review.

Responsiveness

Dr. Hamity explained that applications must be responsive to the Scope and Responsiveness Criteria in the NOFO. Responsiveness will be determined by program staff in collaboration with review staff. Dr. Hamity advised applicants to look for the words "must" and "need" when reading through the NOFO. For example, the NOFO says, "The application must include letters of support from at least three different accredited complementary and integrative health clinical institutions…"

Applications nonresponsive to the terms of the NOFO will not be reviewed. Examples include:

- Applications that do not include an institutional letter of support from the submitting institution.
- Applications that do not include at least three letters of support from partnering integrative health institutions with varying clinical disciplines.
- Applications that do not propose a formal plan for pilot projects.
- Applications that do not include a PEDP.
- Applications that include resources that are not virtually available from remote locations.

Compliance

Compliance factors specific to this NOFO include the following:

- Budget
  - Application budgets may not exceed $850,000 per year in direct costs.
  - Applications must budget for study personnel to participate in an annual meeting.
  - The PI must devote 2.4 person-months to the REACH Center. If multiple PIs are proposed, the combined effort must equal at least 2.4 person-months, and each PI must devote at least 1.2 person-months.
  - Up to $100,000 direct costs per year may be budgeted to support the pilot projects.
- Project period
  - The maximum project period is **5 years.**
- Eligibility
  - Foreign components are allowed, but foreign institutions and non-U.S. components of U.S. organizations are not.
  - Eligible clinical institutions include but are not limited to schools of acupuncture, chiropractic, osteopathy, naturopathy, physical therapy, and music and art therapy.
  - For osteopathic schools, only those that teach manual manipulation as part of the required core curriculum are eligible.
- Page limitations
  - Specific Aims: 1 page
  - **Research Strategy: 20 pages** (an atypical length)
- Allowable appendix material
  - See NOT-OD-17-098 for a list of allowable appendix material.
- Allowable post-submission materials
  - See NOT-OD-19-083 for a list of allowable post-submission materials.
  - The due date is 30 days before the peer review meeting.
  - Information accidentally left out of the application cannot be submitted as post-submission material.

Completeness

To be considered complete, applications must include milestones, a timeline, and a PEDP and are required to comply with the instructions regarding Resource Sharing Plans and Data Management and Sharing Plans.

Review Criteria

- Applications will be scored according to the five standard review criteria (significance, investigator[s], innovation, approach, and environment), and additional review criteria **including milestones** will be taken into account in determining the overall impact score.
- Aspects that reviewers are asked to address match what applicants are asked to address in the application. (See the webinar slides for an example.)
- NOFO-specific language has been added to the five standard review criteria.

Dr. Hamity advised applicants to make sure to read and take into consideration the review criteria when planning their applications.

Review Panel

Applications submitted in response to this NOFO will be reviewed in a special emphasis panel at NCCIH.

Reviewers will be selected based on:

- Specific areas of expertise in the target areas of the NOFO
- Clinical disciplines proposed in the applications

Reviewers will be oriented to use the additional review criteria and the additional review language added to the standard criteria in their assessment.

Dr. Hamity reminded applicants to address how their applications would be impactful considering the goals of the NOFO.

Letters of Intent

Letters of intent should be sent to Jessica McKlveen, Ph.D., NCCIH Office of Scientific Review, at Jessica.McKlveen@nih.gov and should include the following:

- Descriptive title of proposed activity
- Name, address, and telephone number of the program director (PD)/PI
- Names of other key personnel
- Participating institutions
- Number and title of this NOFO

To expedite review, applicants are requested to notify the NCCIH Referral Office by email at Jessica.McKlveen@nih.gov when the application has been submitted. Please include the NOFO number and title, PD/PI name, and title of the application.

Important Dates

- Letters of intent are due **July 30, 2024.**
- Applications are due **August 30, 2024,** and late applications will not be accepted.
- The review meeting will take place in **November 2024.**
- Award decisions will be made in **January 2025.**

Questions and Answers

Q: Can a research hub consist of three or four different institutions who coordinate with each other to provide the services outlined in the NOFO?

A: Dr. Mudd explained that this is allowable. The application should provide strong justification for the partnership and explain how the activities will be coordinated. Letters of support from partners would still be needed. Dr. Mudd advised keeping in mind the requirements for the research environment at the REACH applicant institution.

Q: Will the slides be available for reference after the webinar?

A: Ms. McRae-Williams said that slides would be sent to all registrants by email immediately after the webinar, along with a brief survey.

Q: In response to a question about the number of webinar registrants, Ms. McRae-Williams said there were more than 100.

Q: Does the $100K in pilot funds include indirect costs?

A: No, it does not. Dr. Mudd said that the $100,000 limit applies to direct costs per year. She also explained that Centers may choose to delay pilot projects until the second year if they feel that they need the first year as start-up time.

Q: Will the REACH institutions also support mechanistic and translational research and research training? Do these qualify as clinical research?

A: Dr. Mudd said that the answer is yes. NIH's definition of clinical research includes many types of human subjects research. Human mechanistic and translational research can be included, and so can observational epidemiologic studies and pilot feasibility clinical trials. Animal research cannot be included.

Q: Can homeopathy schools apply?

A: Dr. Mudd said that the REACH Center application must be submitted by the research-intensive institution. Homeopathy schools would fit better as partnering clinical institutions.

Q: Does each partnering clinical institution need to have multiple clinical disciplines? And how many faculty at the partnering institutions must have 20 percent protected time?

A: Dr. Mudd explained that the clinical institutions do not need to have multiple degree programs or clinical disciplines, but the REACH Center must partner with at least three institutions that, as a group, represent a variety of disciplines. The requirement for protected time applies to at least one faculty member per year, but there could certainly be more.

Q: How do you define direct costs?

A: Dr. Hamity explained that direct costs are costs of resources specifically needed for the project, such as salaries, equipment, supplies, and travel. Indirect costs, which are negotiated with the institution, are for things like keeping the electricity on.

Q: What does the activity code U24 mean?

A: Dr. Hamity explained that U24 is a cooperative agreement mechanism that is used when a project will have substantial scientific or programmatic involvement from NIH. Staff from NIH will work directly with the applicant to coordinate the project activities.

Q: Is there an expectation that the PI and co-PI would be from both research-intensive and complementary and integrative health institutions, or can the partnership occur in a different way, such as a steering committee versus investigators?

A: Dr. Mudd said there is no expectation that the partnering complementary and integrative health institutions would participate either as multiple PIs or as co-investigators. Instead, their partnership is substantiated through a letter of support that provides all the required elements shown in the webinar slides and the NOFO. It is possible to also have a steering committee or advisory board, but applicants are not required to include individuals from the clinical institutions as multiple PIs or co-investigators.

Q: What does 2.4 person-months or 1.2 person-months mean?

A: Dr. Mudd explained that 2.4 person-months of effort is about 20 percent of someone's time; 1.2 person-months is 10 percent.

Q: An attendee from a pediatric medical institution expressed an interest in collaborating with others with pediatric interests and asked if they would be eligible to apply.

A: Dr. Mudd said that this attendee would probably be eligible to apply. She suggested that the question would be a good one to address in a one-on-one conversation and invited the individual to email her to set up a time to talk.

Q: Are research-intensive sites mutually exclusive from clinical training sites?

A: Dr. Mudd said she was not sure what the questioner meant by clinical training sites. If the questioner is talking about a residency program, it likely does not fit the environmental requirements of a research-intensive institution. Dr. Mudd asked the questioner to reach out to her individually.

Q: Will NCCIH cover the indirect costs for the subawards (pilot studies)?

A: Dr. Mudd said yes, NCCIH would cover indirect costs for subawards.

Q: For approval of pilot funds, will the REACH Center make recommendations to NIH, and will NIH review them and make suggestions? What is the expected timeline for NIH feedback and recommendations?

A: Dr. Mudd said that the way that decisions about pilot funds will be made is a good example of the substantial programmatic involvement that is characteristic of a cooperative agreement. Once the REACH Center is awarded, an NIH program staff member will be assigned as the project scientist. This individual will have substantial contact with the study team and will be involved in designing the pilot study program. The timeline will be determined by the study team and NIH project scientist together. Because the REACH Center is conducting the pilot study program, applications for pilot projects will not go through the formal NIH review process. Instead, the REACH Center will determine the review process, and NIH program staff will be involved in the decision making.

Q: Can the participating faculty at the clinical institutions be nonteaching academic staff, such as a dean of learning experience design, or do they have to be subject matter experts who teach or supervise the subject?

A: Dr. Mudd said that the partnering institutions can determine who they feel is eligible as faculty. The priority is that the participating faculty should be individuals who are interested in pursuing clinician-scientist careers.

Q: Should the training for complementary and integrative health clinical faculty researchers reflect their career path status, or should each pilot grant be geared toward a future R01 submission?

A: Dr. Mudd said that the research-intensive institution could envision different resources depending on what is appropriate for faculty at the partnering institutions. Some clinical institutions may already have an active research program, and their faculty may be prepared to submit R01-level applications. Others may not have that level of experience, so it would be more appropriate to think in terms of earlier stage applications and smaller projects, such as K, R21, or R15 awards. For both the provision of resources and the pilot program, it is important to consider the needs of the partnering institutions and fit those needs.

Q: Is it permissible for the REACH Center to provide hybrid pilot research opportunities, such as bringing in a pilot PI for training at the research institution and conducting pilot studies primarily remotely? Would this mean that no subaward would be given to the partnering institution?

A: Dr. Mudd explained that the REACH Centers must be virtual resource centers with no geographic limitation. All resources proposed must be delivered virtually. Applicants cannot propose resources that would require faculty from the partnering clinical institutions to come on site at the research-intensive institution for training. The pilot funds are intended for faculty at the partnering institutions, who would conduct the pilot study at their own institution, perhaps in collaboration with others.

Closing Remarks

Ms. McRae-Williams reminded attendees that they would receive slides and a survey shortly after the conclusion of the webinar and a written summary in about 8 days. She urged applicants to follow up with Dr. Lanay Mudd (Lanay.Mudd@nih.gov) for program-related questions and Dr. Jessica McKlveen, director of the NCCIH Office of Scientific Review, with review-related questions. She then closed the webinar.