Technical Assistance Webinar One for the Research Resource Center to Build an Open-Access Repository and Database for Anatomical and Physiological Correlates of Acupoints (RFA-AT-23-005)

October 6, 2022

Purpose of the Webinar

On Thursday, October 6, 2022, the National Center for Complementary and Integrative Health (NCCIH) of the National Institutes of Health (NIH) hosted a technical assistance webinar to share information about the Research Resource Center to Build an Open-Access Repository and Database for Anatomical and Physiological Correlates of Acupoints U24 funding opportunity (RFA-AT-23-005).

Webinar Speakers and Panelists

- Emrin Horgusluoglu, Ph.D., Program Director, Division of Extramural Research, NCCIH
- Shiyong Huang, Ph.D., Scientific Review Officer, Division of Extramural Activities, NCCIH
- Anita McRae-Williams, M.A., Outreach Communications Program Manager, Division of Extramural Research, NCCIH (Webinar Moderator)

Wen Chen, Ph.D., Chief of the Basic and Mechanistic Research Branch in the Division of Extramural Research at NCCIH, also participated in the Q&A portion of the webinar.

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. Participation in this webinar is not a requirement for application submission. Participants should direct any additional questions they might have after the webinar to NCCIHWebinarQ@nih.gov.

Background and Rationale for the Funding Opportunity

Dr. Horgusluoglu explained that in February 2019, NCCIH and the National Cancer Institute held a workshop on translating fundamental science of acupuncture into clinical practice for cancer symptom management, pain, and substance abuse. One major recommendation from this workshop was the need to standardize the anatomical and physiological ontology of acupoints. This need was also addressed in a 2018 journal article by Helene M. Langevin, M.D. (now the director of NCCIH) and Peter M. Wayne, Ph.D.

In the summer of 2019, NCCIH issued a request for information (RFI) to obtain public comments on potential development of an open-access repository or database for anatomical and/or physiological data associated with acupoints. Acupoints were defined as locations on the body that can be stimulated using a variety of methods, not just with inserted acupuncture needles. More than 100 responses were received, with three-quarters of respondents agreeing that a database of this type would be helpful for acupuncture research. Most respondents preferred that the database use either Western anatomy/neuroanatomy references only or both Western and Eastern (traditional Chinese medicine, TCM) references. Most respondents preferred that nomenclature standards for acupoints reflect both the current English/American system and the traditional Chinese system.

Desired Features and Functionality

The desired key features and functionality of the database, based on input from potential users, data contributors, and the research community, include the following:

For development and maintenance of the database:

- Lead experts
- Partnerships with acupuncture or peripheral nerve stimulation organizations
- Serve research community
- Standardized language
- Common data elements
- Select for high-quality data
- Bidirectional translational research

Functionality and additional features:

- Searchable
- Open access
- Notification/update/alert systems
- Compatible with other relevant NIH databases
- Annotation of safety issues and confounding factors
- Practitioner utility

Key Features of the Request for Applications (RFA)

The RFA calls for a research resource center to develop and maintain a repository and database for **commonly used acupoints,** along with key anatomical specifications, as well as integration with other databases with **physiological correlates.**

The proposed repository and database should:

- Be developed and maintained by lead experts of the acupuncture research community partnering with acupuncture or peripheral nerve stimulation organizations, in collaboration with NIH
- Serve the acupuncture research community, including basic research and mechanistic clinical research, by having standardized language, ontology, and common data elements
- Select and deposit high-quality research data and support bidirectional translational research
- Be open access and searchable, and include notifications/update/alert systems
- Be capable of storing, organizing, managing, and tracking access to inquiries and retrievals of the data
- Be compatible with other databases with relevant physiological correlates

Applications for this RFA must include the following four components. Completion of these components must be the basis for milestone-driven deliverables for years 1–2 and 3–5.

1. Development of acupoint ontology
2. Development of the acupoint atlas and repository
3. Integration of physiological database(s) to the developed acupoint atlas and repository
4. Design and development of an integrative database system

Applicants may customize these milestones based on their own database design. (See the slide set for an example of customization.)

It is expected that the acupoint database and repository will be compatible with databases for physiological correlates, such as those of:

- The NIH Common Fund's Stimulating Peripheral Activity to Relieve Conditions (SPARC) program
- The NIH Brain Research Through Advancing Innovative Neurotechnologies (BRAIN) Initiative
- The Human BioMolecular Atlas Program (HuBMAP)
- The GenitoUrinary Development Molecular Anatomy Project (GUDMAP)
- FaceBase (a comprehensive craniofacial database)

RFA Scope and Priorities

Dr. Horgusluoglu explained that applications that include HIV/AIDS-related research, as well as those that are not relevant to acupoints, that do not meet at least the first two of the four components, that have no specified milestones, or that do not include an acupoint ontology, atlas, and repository will be considered not responsive to the RFA and will not be reviewed.

The primary priority of the RFA is development of the open access acupoint atlas and repository. The RFA also supports integration with other databases and development and pilot testing of an integrative database system. The database should be suitable for data from both human and animal subjects/models and should be searchable. The final product should be useful to the acupuncture research community.

Cooperative Agreement Terms and Conditions of Award

This funding opportunity uses a cooperative agreement mechanism, involving collaboration between the funded institution and NIH. After award, NCCIH will assign scientific program staff to assist, guide, coordinate, or participate in project activities.

Letter of Intent

Although a letter of intent is not required and does not enter into the review of a subsequent application, the information that it contains will allow us to plan the review. . The letter of intent should be submitted by October 31, 2022.

Review Considerations

Dr. Huang explained that submissions are due by November 30, 2022, and that applications that are incomplete, noncompliant, or not responsive to the RFA may not be accepted for review. To be sure that your application is responsive, look for "must," "need," and "required" in the Scope and Responsiveness Criteria. For example, the RFA says that applications "must" be driven by milestones.

Applications must comply with the following requirements:

- The budget must reflect actual needs and not exceed $700K direct costs per year.
- The project period must reflect the scope of the project and not exceed 5 years.
- Foreign institutions are not eligible to apply, but foreign components are allowed.

- Applications must adhere to a 1-page limit for specific aims and a 12-page limit for research strategy.
- Requirements include milestones, timelines, and a data sharing plan.
- Applications must comply with requirements for allowable appendix materials. If materials that are not allowed are included, the application may be considered noncompliant.

Dr. Huang explained that post-submission material is allowed for this funding opportunity. Details are given in the slide set and RFA. It is uncertain whether the NIH COVID-19 flexibilities policy that has allowed submission of preliminary data as post-submission material will be extended to the May Council round (the round relevant to this RFA). Applicants should stay informed about changes in this policy.

Reviewers will score applications according to the five standard review criteria (Significance, Investigator[s], Innovation, Approach, and Environment), plus additional review criteria including a study timeline. Language specific to this RFA has been added to the standard review criteria. The aspects of the application that reviewers are asked to consider match those that applicants are asked to address in their applications. (See the slide set for an example.) A Special Emphasis Panel at NCCIH will review the applications. Reviewers will be selected based on specific areas of expertise in the target areas of the RFA and the science proposed in the applications.

Applicants should keep in mind the need to address how their applications would be impactful considering the goals of the RFA.

Important Dates
- Letters of intent are due **October 31, 2022.**
- Applications are due **November 30, 2022.**
- A review meeting will be held in **February 2023.** Late submissions may be considered in some situations.
- The earliest start date is **August 2023.**

Questions and Answers
Q: May I submit post-submission materials?

A: Yes. They must be submitted no later than 30 calendar days before the review meeting. They require concurrence of the authorized organization representative and must follow the instructions about allowable post-submission materials.

Q: What animals should be included in the database?

A: The RFA does not specify the types of animals. Applicants should explain the relevance of the animal model they have chosen.

Q: If only one proposal will be funded, will NCCIH combine elements from different proposals into it?

A: NCCIH will not combine elements from different proposals. Applicants who wish to seek collaborators may participate in a [networking and collaboration webinar](#) for this funding opportunity, to be held October 21, 2022. Details are given at the end of this summary.

Q: Is there a way for us to learn about interested parties whom we can collaborate with?

A: The October 21 [networking and collaboration webinar](#) will provide the opportunity to meet with potential collaborators.

Q: Do you anticipate the need for the repository to be able to store experimental data?

A: Inclusion of experimental data is welcome if it is peer-reviewed, published data of high quality. It is important to consider how you will evaluate the quality of the data that go into the repository.

Q: Can you clarify whether an international organization is eligible?

A: Foreign institutions are not eligible to apply, but inclusion of foreign components is 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 or not 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.

Q: Are animal models and studies required or expected?

A: The database should be suitable for data from both humans and animals in an open-access and searchable format. Inclusion of animal data is highly preferred so that the database can support mechanistic and translational clinical research. The choice of animal model should be determined by factors that include the availability of high-quality data and potential connections to other databases.

Q: What are the criteria for high-quality data?

A: We feel that NCCIH should not define which data are high quality. The research community should decide. You should include an explanation of which data you consider high quality and how you will ensure that data in your database are high quality in your application.

Q: Does the Eastern nomenclature system of acupoints only refer to Chinese?

A: The language used should be English, but the nomenclature system should include both Eastern and Western anatomical references.

Q: Can we include proven research from other countries?

A: Yes, proven research from other countries can be included. Applicants will need to explain how they will determine which research is "proven" or "high quality."

Q: Will the networking session be held in person, and how can we get more information about it?

A: The networking session will be a virtual event. The final slide in the slide set provides full information. You can also visit this webpage for further details.

Q: Can you provide examples of high-quality research data?

A: The data included in the databases of physiological correlates mentioned earlier, such as BRAIN and SPARC, are good examples of high-quality data, and NCCIH would like the data in the acupoint database to be of comparable quality.

Q: Are for-profit organizations and small businesses eligible for this RFA, and can they be involved in a team of co-principal investigators (co-PIs)?

A: Small businesses and other for-profit organizations are eligible to be co-PIs for this RFA.

Q: Is there an expectation for where the imaging data, such as magnetic resonance imaging (MRI data), should come from?

A: The whole person imaging data provided in the slide set for this webinar are just examples. Applicants are welcome to include their own whole person imaging datasets in their applications.

Q: Is the scope of the RFA restricted strictly to acupuncture, or can it extend to other types of external therapy delivery? Also, can controversial or experimental points be included?

A: For this RFA, we are looking for acupoints. But that does not just mean acupuncture. Other therapies that stimulate acupoints but do not use acupuncture needles that penetrate the skin are within the scope of this RFA. The paper by Langevin and Wayne gives a good idea of the kinds of acupoint therapies that might be included.

Q: Can preliminary data be submitted as post-submission material?

A: NIH has permitted this for the last few submission rounds as part of the COVID-19 flexibility policy. For this RFA, we are waiting to hear whether it will continue to be allowed for the May 2023 Council round (the one that is relevant to this funding opportunity).

Q: Will the ontology and psychological description relate to both biomedical and TCM systems?

A: The atlas should use Western anatomical references. Whether to also include the TCM system is up to the applicant, but the Western references are required. Physiological descriptions must match those in the NIH databases referred to earlier, such as BRAIN or SPARC. This is not an initiative to build a physiological database. The goal is to make connections to existing NIH-supported physiological databases. This question is complex, and applicants may want to seek additional clarification. For more information, contact Dr. Horgusluoglu by email at nccihacuptdatabase@mail.nih.gov .

Q: What is the plan for the maintenance of these databases?

A: Applications should include a maintenance plan. It is intended that the database be long term and open access for the research community. The goal is to relate acupoints to specific organ systems and physiological outcomes.

Q: Should the nomenclature include details or aspects of therapy for reproducibility, such as needle acupuncture?

A: All details needed for reproducibility should be included.

Q: Is it necessary for the PI to have a doctoral degree?

A: No. Any individual with the skills, knowledge, and resources necessary to carry out the proposed work may apply. However, to be competitive, the applicant should have a strong history of Federal research funding. Someone without a Ph.D. or other doctoral-level degree is probably at a career stage where they do not have such a history and therefore may not be reviewed strongly as a potential PI.

Q: In addition to anatomy and physiology, should cell biology and quantum theory be included?

A: If the applicant feels that these additional topics are relevant, they could propose including them, but it is important to be aware of how this might be reviewed. The high-quality aspect of the data will come into play during review.

Q: Should the application include tapping into acupuncture with neuroanatomy?

A: You can include neuroanatomy, but NCCIH is looking for anatomical data for the whole person as well, not just neuroanatomy.

Q: Does this RFA apply only to human subjects?

A: No. The database should be suitable for data from both humans and animal models.

Q: Are there metrics regarding the functionality of the existing databases with which this one will interface—for example, regarding how many users are successfully using the database and the types of uses? Should these metrics be built into the database?

A: The physiological databases are relatively new. In the past, their use has been restricted mostly to their own investigators. The creators of the databases intend to broaden their availability, which is why we want to leverage them. If you can obtain data on the number of users, it could be helpful, but because the databases are new, this information may not be available.

Information About the Networking and Collaboration Session on October 21, 2022

A researchers networking and collaboration webinar for this RFA will be held on **October 21, 2022,** from **3 to 4 p.m. ET.** This virtual networking session will provide an interactive team-building experience for potential applicants. Participants will have the chance to have facilitated conversations with NCCIH program officials and topic experts related to technical requirements of the RFA. You can register for this session on Eventbrite.