

Funding Opportunity: Force-Based Manipulation (ForceNET) Pilot Awards

https://sites.duke.edu/forcenet/

What is ForceNET? ForceNET is a network community that exists to connect interdisciplinary force-based manipulation (FBM) researchers and/or clinicians of diverse backgrounds to address notable gaps in mechanistic-related knowledge, create a platform for sharing and dissemination of this knowledge, financially support pilot research to address identified mechanistic knowledge gaps, and when appropriate, frame and integrate the new knowledge into a clinical context.

Force-based manipulation involves the application of forces to the body with or without a therapeutic intent. Force-based manipulation approaches include manipulation and mobilization and/or touch-based techniques such as massage. These FBM approaches are proposed to exert their effect through biomechanical, neural, and contextual (psychosocial) *mechanisms* associated with their application. **By definition**, *mechanisms* **reflect the actions of an intervention (biological or behavioral)**, and how those actions unfold. There is currently a notable lack of understanding of the underlying mechanisms in FBM. At present, knowledge gaps include an understanding of how force application mediates downstream effects, how spinal and supraspinal circuits' process input from FBM, how mechanosensitive receptors, neurons, and circuits subjected to FBM change in pathological conditions, and how contextual factors interact with therapeutic forces. These mechanistic gaps in knowledge manifest as *barriers* toward collaboration between the scientists that study FBMs and lead to unmet opportunities for scientists and professionals who do not presently investigate FBMs.

ForceNET is funded by the National Center for Complementary and Integrative Health (NCCIH) and the National Institute of Neurological Disorders and Stroke (NINDS) (U24AT011969). Principal Investigators are William R. Reed DC, PhD, Associate Professor and Director of the Rehabilitation Science Program, School of Health Professions, University of Alabama at Birmingham and Chad Cook PT, PhD, Professor and Director of Clinical Research Facilitation, Duke University. Co-Investigators, Greg Kawchuk DC, PhD, Professor in the Faculty of Rehabilitation Medicine, University of Alberta; and Vitaly Napadow PhD, Professor of Physical Medicine and Rehabilitation, as well as Radiology, Harvard Medical School, and Medha Pathak PhD Associate Professor University of California, Irvine.

Funding Opportunity Title: Force-Based Manipulation (ForceNET) Pilot Awards

The ForceNET network invites inter-disciplinary applications for **1 year pilot awards (up to \$75,000 total costs)** to provide project support for new or established investigators interested in FBM research. Pilot applications must propose to support small-scale pilot projects to develop data, theoretical frameworks, or empirical methods, or support the development of novel approaches requiring interdisciplinary collaboration. ForceNET pilot projects may involve primary data collection, or- secondary data analyses on existing datasets related to FBM mechanistic research.

Human subject studies involving high-risk populations or high-risk interventions are prohibited for small pilot grants.

• ForceNET High Priority Areas:

- <u>FBM Biomechanical Metric Development</u> to characterize and quantify the types of in vivo superficial or deep mechanical forces associated with FBM application using universally accepted scientific metrics and terminology.
- FBM Neural Mechanosensory Transduction (physiological mechanisms)- to identify multiscale

responses (molecular, cellular, and/or neural circuit mechanisms) that underlie the physiological effects, mechanosensory transduction, and/or biological response related to Force-Based Manipulations.

• **FBM Psychosocial/Contextual Mechanisms** – to identify how contextual factors interact with therapeutic forces. Examples of psychosocial/contextual factors of interest include, but are not limited to: (social touch, patient/clinician relationship for delivery of therapeutic forces, etc. and should be investigated using quantifiable psychological or human neuroimaging metrics). Self-reported clinical outcomes as primary measures should not considered to be applicable to this RFA, but they may be included among secondary outcomes.

Applications that focus on non-mechanistic research or clinical/patient centered outcomes will be considered <u>nonresponsive to this call</u>. By definition, *mechanisms* reflect the actions of an intervention (biological or behavioral), and how those actions unfold. We encourage applicants to visit the ForceNET website (<u>https://sites.duke.edu/forcenet/</u>) short videos describing "What is Force-Based Manipulations" and "What is Mechanistic Research". Certain aspects of acupuncture studies may qualify for this RFA, but applicants must make a clear connection of how their intended study addresses one of ForceNET's aforementioned three high-priority areas.

ForceNET RFA IMPORTANT DATES

Key Dates:

Posted: April 1, 2024 Expiration Date: Oct 2, 2026 Funding Amount: up to \$75,000 total costs available* (funding for 1-2 grants/year is anticipated) Letter of Intent Due: September 1, by 11:59 PM (EST) (Earlier LOI submissions are encouraged to provide feedback on the grant application). Due: October 1 by 11:59 PM (EST) -Annual grant application submission dates

*The ForceNET pilot award funding mechanism offered through NCCIH grant #U24AT011969.

<u>Eligibility</u>. Investigators may contact the ForceNET Pilot Working Group leader (William Reed; wreed@uab.edu) to determine their eligibility and appropriateness of their project.

Principal Investigators must be:

1). Members of the ForceNET network. There is no financial cost to join ForceNET, please complete the brief membership form at (<u>https://sites.duke.edu/forcenet/</u>)

2). Eligible to submit a grant to NIH and to receive NIH funding. Foreign Institutions (non-domestic) entities are **not eligible** to apply. Non-domestic (non-U.S.) components of U.S. organizations **are not eligible** to apply.

3). Foreign components (**e.g., international collaborators and consultants**), as <u>defined in the *NIH Grants Policy Statement*, **are** allowed.</u>

4). Have a faculty or regular rank academic appointment.

• Investigators at any stage of their career may apply.

Additional consideration will be given to:

- a) Early career stage investigators (as PI).
- b) Collaborative interdisciplinary efforts between public/private universities and Integrative Medicine Institutions (.i.e., chiropractic, massage, acupuncture, etc.)

Amount and Period of Support

Funding will be provided for one year with the possibility of a six-month no-cost extension. Funding is available in an amount of up to \$75,000 total costs. All pilot projects solicited through this funding opportunity will be made as a fixed amount subaward of the parent U24 grant. Funds are encouraged to be used for all costs directly towards the research project including:

- a. Faculty salary
- b. Research-related costs (e.g., participant incentives, lab supplies)
- c. Fees for database access
- d. Contracts for research-related service (e.g., recruitment services, survey administration)
- e. Small equipment costs
- f. Publication costs
- g. Travel to NIH/U24 sponsored conference/symposium to present work.

The number of awards will depend on the requested budgets, availability of funds, and the receipt of a sufficient number of high-quality proposals.

Application Submission Process

Letter of Intent

Interested applicants must submit a letter of intent that includes the following information:

1. 1-page with title and description of the project (max. 300 words), relevance to FBM mechanistic research, and names of investigators/institutions. LOIs should be single-spaced, with at least 0.5-inch margins, and should use 11point Arial or Times fonts.

2. Submit LOI by September 1, 11:59 PM (EST) via ForceNET website. File name should read:

"ForceNET,Year,PI Last Name" - Please do not use hyphens or underscores. If you do, you will receive an error from the submission website.

3. LOIs will be evaluated regarding relevance to one or more of the three ForceNET mechanistic research priorities. If the project is not relevant to this particular RFA, the investigator will be contacted and constructive feedback will be provided as warranted. Early LOI submissions are encouraged.

Items 1-6 should not exceed 5 pages.

Pilot Grant Application

Applicants should submit the documents below in a <u>single</u> PDF file. Applications should be single-spaced, with at least 0.5-inch margins, and should use 11-point Arial or Times fonts. **The SINGLE PDF file should contain:** 1. PHS 398 Face Page (signed by authorized institutional official).

- 2. PHS 398 Budget pages 4 & 5
- 3. NIH Biosketch (key personnel only) -5 page limit
- 4. Abstract. A 300 word abstract summarizing the pilot project and the relevance to FBM mechanistic research.

5. Research Proposal-Specific Aims (**1 page**), Significance/Innovation, Preliminary Data if any, and a brief description of Methods (**3-4 pages**).

6. Planned Extramural Grant Application (**one paragraph**). Description and timeframe of NIH extramural grant proposals that will be anticipated to be submitted as a result of this seed funding. Include the specific NIH funding agency, grant mechanism (e.g. R03, R21, R01, K99), and expected submission date.

7. References (no page limit)

8. Resources / Environment (1 page)

9. Budget and budget justification (no page limit). Include description of expertise of investigators/mentors and research staff. The pilot award funds must go directly towards the research project. Funds may be used for all costs directly associated with completion of the research project including applicant and research staff (if proposed) salaries and fringe benefits, project-related research costs (e.g., participant incentives, survey recruitment and administration, printing), database access, small equipment, travel (for data collection and/or conference attendance), conference registration.

10. NIH Biosketch (key personnel only) -5 page limit

11. Other Support (key personnel only)

12. JUST-IN-TIME information. If you are notified that your application is under consideration for funding after the initial ForceNET review panel, then the following documents must be added to your original SINGLE FILE PDF (and re-submitted) before complete evaluation and any funding decision can be made.

If animal models are involved, the pilot project application should provide a description of the plan use of animals in the project, Institutional Animal Care and Use Committee (IACUC) approval in the same file with select PHS pages. If human subject research is involved, the PHS398 Human Subjects and Clinical Trials Information page Institutional Review Board (IRB) approval from the institution and human subjects training (e.g., CITI) for all involved in the human subjects study should be included in the same PDF as the other required documents. In addition, ForceNET will send the following templates to the applicant(s) to complete: Data and Safety Monitoring Plan (DSMP) and Study Accrual and Retention Plan (SARP). Applicants should recognize that IACUC or IRB approval may require a considerable amount of time, so it is strongly recommended that documents be submitted to your institution at the time of your application

submission to avoid prolonged processing delays.

Review Process

1. Each application will be assessed by a ForceNET panel of cross-institutional peer reviewers.

2. Evaluation Process:

a). Applications that meet eligibility requirements will be reviewed using the following criteria: (1) relevance to FBM research and ForceNET research priorities; (2) standard NIH review criteria (Overall Impact, Significance, Investigators, Innovation, Approach (e.g., study design and procedures, data management, and statistical analysis) and Environment, and (3) probability of developing/strengthening a line of research and of future funding. The highest priority will be given to those requests that are deemed most promising to receive extramural funding.

b). Funding decisions will be made by the ForceNET executive committee based on combined reviewer assessments and programmatic considerations, and in consultation with NIH/NCCIH staff. However, in some cases where the application may represent a conflict of interest or lack clarity in its evaluation, the ForceNET Pilot Grant Working Group will ask for additional review evaluations.

3. If applicable, applications with fundable scores will be required to demonstrate human subjects or IACUC research compliance to NIH standards prior to receiving funding.

Expectations of ForceNET Pilot Recipients during the funding period

Funds will be awarded as subcontracts from University of Alabama Birmingham. For Multi-PI projects between institutions, applications should be submitted with a PI designated from each institution. If invited for a full application, each PI/institution will submit their own budget and scope of work; however, the total costs for the entire project may not exceed \$75,000.

1. PI agrees to prepare an NIH grant application with a goal of submitting at least one manuscript related to the project. Scientific presentations and publications related to this application should acknowledge ForceNET/NIH funding with acknowledgement of NIH grant number.

Investigators will present updates every 3 months at virtual Network meetings and will submit a one-page written scientific report and fiscal report by December 31st for inclusion in the U24 progress report.
A final progress report which includes summary of findings must be submitted to ForceNET at 12 months

past the funding date. The summary should include details of anticipated NIH submission (e.g. R03, R21, R01, K99).

4. PI or other team member agrees to present research findings at a ForceNET and/or NIH steering committee meeting (virtually or in-person).

For RFA-related questions, please contact MPI and Pilot Grant Working Group Leader (Dr. William Reed) or U24 MPI (Dr. Chad Cook) at:

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