Wake Forest Center for Biomedical Informatics and
North Carolina State University Data Science Academy
Request for Applications for Pilot Awards

Purpose

The Wake Forest Center for Biomedical Informatics (WFBMI) and The North Carolina State University Data Science Academy (NCStateDSA) is seeking proposals for innovative and translational informatics solutions to wearable healthcare technology and biomedical research problems. We highly encourage submission of novel **wearable-related technologies** that leverage one or more **informatics tools and methods.** This includes but is not limited to testing the feasibility of novel approaches as well as unconventional solutions to wearable technological research problems**.**

The WFBMI and NCStateDSA will fund pilot studies that address gaps in knowledge or other barriers to wearable technology research. This RFA is intended to elicit proposals that evaluate strategies in one of the following focus areas: 1) Creation, evaluation, and implementation of wearable medical technologies and associated systems; 2) Improving and/or evaluating electronic data capture and data access for clinical and translational research projects as well as patient-reported data; 3) Development of new or improvement of existing analytical methods to gain knowledge and/or discovery from wearable medical technology biomedical data; and/or 4) Creation of informatics tools to improve data discovery, data access, data quality, data provenance and/or reproducible research.

WFBMI and NCStateDSA will fund one project. Successful pilots will receive up to **$40,000**, to be spent within a **12-month project period.** Funds will be split evenly between the WFBMI and NCStateDSA researchers ($20,000 to WF, $20,000 to NCState). Subawards will not be allowed. Note to NC State researchers that the project period will cross the NC State fiscal year, so please indicate in your budget which items will be expended in FY 22-23 and which in FY23-24. Rollover and no-cost extensions will not be allowed.

Successful proposals will clearly state:

- How to create, evaluate, or implement medical science and engineering tools and algorithms.
- A rationale for local relevance and potential for generalizability.
- How the proposed project advances research in Wearable Medical Technology.
- Translational roadblocks that the proposed project will address and the anticipated benefits of overcoming them with informatics.
- A reasonable project plan that is feasible to complete in the project period.

Additionally, successful proposals will exemplify the following characteristics:

- Propose a data science-focused research problem.
- Explain why the research is important, novel, and had the potential for impact.
- Explain why the team and the research are interdisciplinary and how that interdisciplinarity adds to the capability of the research team.
- Propose an actionable component related to diversity, equity, or inclusion that goes beyond the basic expectations of a research group.
- Explains the research aims in a way that is clear, compelling, and understandable to a general scientific community.

Eligibility

These awards are open to all faculty with a rank of instructor or higher from Wake Forest (Health Sciences & University) and North Carolina State University (Data Science Academy). Each collaborative research team must be comprised of members *from both WFBMI and NCStateDSA*.

Key Dates

Date	Detail
12/20/2022, 11:59 pm	Full Application Deadline
1/30/2023	Selection of Awardees
3/1/2023	Project Start Date
2/29/2024	Latest Project End Date

Funding

The Wake Forest Center for Biomedical Informatics and the Data Science Academy will fund up to a total of $40,000 in direct costs for the project, split between the institutions. See section on Budget Guidelines for more details on allowable and non-allowable budget items. Since Center for Biomedical Informatics funds cannot be carried over from one budget period to the next, requests for no-cost extensions will not be approved. As stated above, the project period will cross the NC State fiscal year, so please indicate in your budget which items will be expended in FY 22-23 and which in FY23-24. Rollover and no cost extensions will not be allowed.

Application Procedure

Full Application Deadline: 12/20/22, 11:59 pm

Investigators are invited to apply by submitting their application through the ePilot electronic submission system, by the deadline noted above. Application instructions are summarized below.

Format Specifications

- Arial font and no smaller than 11 point
- Margins at least 0.5 inches (sides, top and bottom)
- Single-spaced lines
- Consecutively numbered pages

Submission/Applicant Information

- Project Title
- Submitting Investigator, Co-Investigator(s), and other Key Personnel information

Abstract (300 words max) that should be readable by a non-technical audience.

Research Plan (6 pages max)

- *Specific Aims*
- *Significance* – Explain how the project addresses an important problem, how it will improve scientific knowledge, technical capability and/or clinical practice.
- *Investigator(s)* – Describe how each member of the team will contribute to the project. Include their expertise and experience that will be utilized on this project.
- *Innovation* – Explain how this project uses novel concepts, approaches or methodologies, instrumentation or interventions.
- *Approach* – Describe the overall strategy for this project, including potential problems, alternative strategies and benchmarks for success, including the diversity, equity and inclusion component(s).
- *Projected Timeline* - (examples can be found in Appendix I)

References (no page limit)

Information Regarding Human Subjects

Address the following if the project **involves human subjects**.

- Provide a one-page document addressing the Protection of Human Subjects, if applicable.
- IRB Approval Status (please note: IRB approval is not required for full application submission, however **a delay in IRB approval does not alter the project end date.**)

Information Regarding Live Vertebrates

- IACUC Approval Status (please note: IACUC approval is not required for full application submission, however **a delay in IACUC approval does not alter the project end date**)

Budget and Justification (budget template plus 1-page justification)

- Complete the budget template form provided along with a brief justification for the funds requested for this RFA. Please include an explanation of other resources that may be leveraged to support the project.

- Sub-awards to other institutions to carry out work on a project are not allowed.

NIH-style biographical sketch for all Key Personnel (new style)

Budget Guidelines

The budget period is for 12 months ending no later than February 29, 2024 Up to $40,000 in direct costs may be requested, with a maximum of $20,000 to WF and $20,000 to NC State researchers. As stated above, the project period will cross the NC State fiscal year, so please indicate in your budget which items will be expended in FY 22-23 and which in FY23-24. Rollover and no cost extensions will not be allowed.

Grant funds may be budgeted for:

- Research support personnel (including undergraduate and graduate students)
- Travel necessary to perform the research
- Small equipment, research supplies, and core lab costs, or
- Other purposes deemed necessary for the successful execution of the proposed project

Grant funds may **not** be budgeted for:

- Faculty or other investigator efforts
- Office supplies or communication costs, including printing
- Meals or travel, including to conferences, except as required to collect data
- Professional education or training
- Computers or audiovisual equipment, unless fully justified as a need for the research
- Manuscript preparation and submission, or
- Indirect costs
- Sub-awards to other institutions to carry out work on a project are not allowed.

Awarded funds must be used to conduct the work proposed. All direct charges to this award must adhere to federal regulations and requirements regarding the use of Center for Biomedical Informatics and NC State funds. The funding parties reserve the right to revoke funding in the event it is determined that funds were not spent in accordance with the approved protocol. The general criteria for determining allowable direct costs on federally sponsored projects are set forth in 2 CFR Part 200: Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards (The Uniform Guidance).

Review Criteria and Process

WFBMI and NCStateDSA proposals are competitive and peer-reviewed. Proposals will be evaluated by Center and Academy Leadership and based on NIH review criteria and scoring. Final award approval will be at the recommendation of the Center and Academy Leadership.

Funding decisions will be made based on the reviews of an evaluation of the projects' connection with the goals of the Center for Biomedical Informatics and NC State Data Science Academy. Any IACUC and/or IRB protocols must be approved prior to the funding of the approved pilot.

Reviewers will score applications from 1 to 9 based on:

1. Significance of the problem to be addressed;
2. Innovation in the proposed solutions;
3. Strength and breadth of the investigative team;
4. Methodological rigor and feasibility with clear milestones;
5. Likelihood that the innovation will be broadly applicable and have an impact on translational research;
6. Clear and understandable communication of the proposed idea;
7. Attention and actionable plan with respect to diversity, equity and inclusion in the research;
8. A reporting plan regardless of whether the study yields positive or negative results;
9. Other elements to be considered in the review include: the likelihood that the investment will lead to external funding or a licensable innovation, early-career faculty involvement, interdisciplinarity, race/gender inclusiveness of the research team, and inclusion of women, minorities, older adults, and children as potential participants.

Program Expectations

If any significant issues arise, the study team will be required to work with the Center for Biomedical Informatics and NC State Data Science Academy to define an intervention strategy for the study to be successfully completed (or in rare cases, terminated).

Specific Deliverables Include:

- Disclosure of implementation/dissemination results and efforts to seek extramural funding beyond the pilot grant and subsequent notification of any funds obtained and/or related publications or significant collaborations from the project for a minimum of 4 years.

Other Guidelines

1. Prior to receiving funds, research involving human subjects must have appropriate approvals from the IRB. Either an IRB approval letter or an IRB response to a "Determination Whether Research or Similar Activities Require IRB Approval" must be submitted to the Center for Biomedical Informatics and NC State Data Science Academy prior to funds being released. Human subjects must be reviewed in accordance with the institution's general assurances and HIPAA. All key personnel must have certification of training in the protection of human subjects prior to the start of the grant period.
2. Prior to receiving funds, research involving live vertebrates must have appropriate approvals from IACUC. Either an IACUC approval letter or documentation on why the activity does not require IACUC approval must be submitted to the Center for Biomedical Informatics and NC State Data Science Academy prior to funds being released.
3. Center for Biomedical Informatics and NC State Data Science Academy staff will work closely with funded teams throughout the grant period to monitor progress and, when necessary, provide assistance. A final progress report will be required. We expect PIs to report over the lifetime of the work the outcomes achieved due to the pilot award, e.g., subsequent external funding, publications, presentations, and patents.
4. All publications that are the direct result of this funding must reference: "Research reported in this publication was supported by the Center for Biomedical Informatics, Wake Forest School of Medicine and the Data Science Academy, North Carolina State University." Publications must also be registered in PubMed Central.
5. Any awardee who leaves his or her position should contact the Center for Biomedical Informatics and NC State Data Science Academy to discuss future plans for the project.

Grant Administration

The Principal Investigator is responsible for the administration of grant funds. Projects will be for a 12-month period of time.

Contacts

Questions about your proposed research project should be directed to WFBMI (WFBMI@wakehealth.edu).

Questions about the ePilot electronic submission system should be directed to Jessie Barnett, jcbarnet@wakehealth.edu

Appendix I

Below are examples to show different methods to provide study milestones, outcomes, and timelines. However, these formats are not required.

Example 1:

- **Milestone 1 (0-1.5 months):** Milestone 1 Details **Outcome:** Outcome 1 Details
- **Milestone 2 (1.5- 4 months):** Milestone 2 Details **Outcome:** Outcome 2 Details

Example 2:

Timeline and Milestones				
Month	1	2	3	4
Activity/Aim/Milestone 1	X	X	X	
Activity/Aim/Milestone 2	X	X		
Activity/Aim/Milestone 3		X	X	X

Example 3:

Aim	**Milestone**	**Month 1-2**	**Month 3-4**
1	Milestone 1	X	
	Milestone 2	X	X

Aim 1 Anticipated Outcomes: Detail

Aim	**Milestone**	**Month 1**	**Month 2-4**
2	Milestone 1		X
	Milestone 2		X

Aim 2 Anticipated Outcomes: Detail

Aim	**Milestone**	**Month 1-3**	**Month 4**
3	Milestone 1		X
	Milestone 2		X

Aim 3 Anticipated Outcomes: Detail