Wake Forest Center for Biomedical Informatics Request for Applications for Pilot Awards

Purpose

The Wake Forest Center for Biomedical Informatics (WFBMI) is seeking proposals for innovative and translational informatics solutions to healthcare and biomedical research problems. Novel technologies, including but not limited to, testing the feasibility of novel approaches as well as unconventional solutions to translational research problems by leveraging one or more **Informatics tools and methods** are highly encouraged.

The WFBMI will fund two informatics pilot studies that address gaps in knowledge or other barriers to translational research. This RFA is intended to elicit proposals that evaluate strategies in one of the following focus areas: 1) Creation, evaluation, and implementation of Clinical Decision Support or Computer-assisted Diagnosis Systems; 2) Improving and/or evaluation of 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 multi-dimensional biomedical data; and/or 4) Creation of informatics tools to improve data discovery, data access, data quality, data provenance and/or reproducible research.

The WFBMI will fund two projects. Successful pilots will receive up to \$25,000, to be spent within a 12-month project period.

Successful proposals will clearly state:

- How to create, evaluate, or implement Biomedical Informatics tools and algorithms
- A rationale for local relevance and potential for generalizability
- How the proposed project advances research in Biomedical Informatics
- 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.

Eligibility

These awards are open to all faculty with a rank of instructor or higher from Wake Forest (Health Sciences & University). The research team must be members of WFBMI.

Key Dates

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Date	Detail		
12/18/19, 11:59 pm	Full Application Deadline		
02/14/2020	Selection of Awardees		
03/01/2020	Project Start Date		
04/30/2021	Latest Project End Date		

Funding

The Wake Forest Center for Biomedical Informatics will fund up to \$25,000 in direct costs for each project. 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.

Application Procedure

Full Application Deadline: 12/18/19, 11:59 pm

Investigators are invited to apply by submitting their application through the <u>ePilot electronic submission</u> <u>system</u>, 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)

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.
- 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 <u>not required</u> 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 <u>not required</u> 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 <u>budget template form</u> provided along with a brief justification for the funds requested for this RFA. Please include 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 04/30/2021. Up to \$25,000 in direct costs may be requested.

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 effort
- 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

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 funds. The Center reserves 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 is 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 proposals are competitive and peer reviewed. Proposals will be evaluated by Center Leadership and based on NIH review criteria and scoring. Final award approval will be at the recommendation of Center 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. Any IACUC and/or IRB protocols must be approved prior to 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 the innovation will be broadly applicable and have impact on translational research, and;
- 6. A reporting plan regardless of whether the study yields positive or negative results;
- 7. 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, 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 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 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 activity does not require IACUC approval must be submitted to the Center for Biomedical Informatics prior to funds being released.
- 3. Center for Biomedical Informatics 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." Publications must also be registered in PubMed Central.
- 5. Any awardee who leaves his or her position should contact the Center for Biomedical Informatics 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 (<u>WFBMI@wakehealth.edu</u>) (6-6861).

Questions about the ePilot electronic submission system should be directed to Brittney Jackson (britjack@wakehealth.edu).

Appendix I

Below are examples to show different methods to provide study milestones, outcomes, and timeline. 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		Χ	Χ	
Activity/Aim/Milestone 2		Χ		
Activity/Aim/Milestone 3		Χ	Χ	Χ

Example 3:

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

Aim 1 Anticipated Outcomes: Detail

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

Aim 2 Anticipated Outcomes: Detail

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

Aim 3 Anticipated Outcomes: Detail