

Wake Forest University and Wake Forest University School of Medicine Request for Applications for Wake Forest Intercampus Collaborative Grant (ICG) Award

Purpose

The goal of this initiative is to foster interdisciplinary research collaborations that spark long-term projects that can garner external funding for novel ideas to benefit human health.

Collaborations may be formed by expanding existing interdisciplinary teams or establishing new teams to carry out a proposed project. Applications must include investigators from Wake Forest University and Wake Forest University School of Medicine (Winston-Salem and/or Charlotte). Preliminary/pilot data are not required to be competitive for this funding mechanism, however available supporting data from literature may be cited.

This pilot mechanism is open to all research types, ranging from mechanistic basic science to population-based projects. Projects relating to advancing our goal to emerge as a preeminent Academic Learning Health System are encouraged. Projects focused on biology and treatment of under-served populations or which address specific needs of our clinical population will be prioritized.

Funding

Up to five projects will be funded and each project will receive up to **\$50,000** in direct costs. Projects will be funded equally from WFU and WFUSM. All projects must meet the above specifications outlined above. All funds are to be spent within a one-year project period.

Eligibility

Applications must be led by faculty with appointments from Wake Forest University (WFU) and Wake Forest University School of Medicine (WFUSM). Projects with shared leadership from WFU and WFUSM are strongly encouraged. Faculty with visiting appointments are not eligible to serve as one of the Principal Investigators.

Key Dates

Date	Detail
06/30/23, 11:59 pm	Full Application Deadline
07/31/23	Selection of Awardees
09/01/23	Project Start Date
08/31/24	Project End Date

CTSI Resources Available to Support Investigators

Several resources are available in the CTSI to help submit a strong application; while they are not required as part of the submission, investigators are encouraged to seek out additional assistance. All services can be requested through the [CTSI Service Request](#) form.

- **Grant Proposal Editing:** have an expert medical editor review your proposal prior to submission. They will offer suggestions on how to refine your writing and thinking. Your proposal will be edited in “track changes” so that you can easily accept or reject edits (free to everyone).
- **Biostatistical Support:** meet with a statistician to develop your study design, measurement, and statistical analysis plans prior to submission (free to everyone).
- **Informatics:** optimization of the EMR to extract data for research purposes (free or fee-for-service, depending on need).

Application Procedure

The full application should be submitted through the [ePilot electronic submission system](#) by the deadline noted above.

Full Application Deadline: 06/30/23, 11:59 pm

Investigators should submit a full application by **06/30/23**. **Applications received after 06/30/23 will not be reviewed.** Application instructions are included in the ePilot system and summarized below.

Applications that do not comply with these guidelines will not be considered for review.

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 Principal Investigators, Co-Investigator(s), and other Key Personnel information

Abstract (300 words max)

Research Strategy (6 pages max, all items below are required components)

- Specific Aims
- Research Plan:
 - Significance
 - Innovation
 - Approach
 - Study Team
- Study milestones and anticipated outcomes (e.g. publication, presentation, grant submission, patent) with timeline (see [Appendix I](#) for examples)

References (no page limit)

Information Regarding Human Subjects

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

- IRB Approval Status (please note: IRB approval is not required for full application submission). Subsequent IRB status will be decided by the Wake Forest University School of Medicine IRB committee.
- Clinical Trial Classification Questions
 - If your project requires an IND/IDE submission or exemption, please consult with Issis Kelly Pumarol at ikellypu@wakehealth.edu for support and to discuss timelines. The timelines can impact your full project timeline and should be considered in the project plans.
- Protection of Human Subjects
 - Needs to clearly describe risk, protections, benefits, and importance of the knowledge to be gained by the revised or new activities as discussed in Part II of NIH competing application instructions
- [Inclusion of Individuals Across the Lifespan](#)
- Inclusion Plans for Women, Minorities, and Children, if applicable
- Recruitment and Retention Plan
- Targeted Enrollment Table (using [NIH Targeted Enrollment Table](#))
- Data and Safety Monitoring Plan (DSMP) and Board (DSMB), if applicable
 - If you are unsure how much safety monitoring your study will need, please contact the CTSI DSMB Administrator, Issis Kelly Pumarol, at ikellypu@wakehealth.edu.

Information Regarding Live Vertebrates

Address the following if the project **involves live vertebrates**.

- IACUC Approval Status (please note: IACUC approval is not required for full application submission)

- IACUC approval will be required (as 'just in time' information) for implementation of projects with live vertebrate animals

Budget and Justification (budget template plus 1 page justification)

- Complete the [budget template form](#) and a brief justification for the funds requested. Please explain how other resources may be leveraged to support the project. If the proposed research will be done on more than one campus/institution, please include details in the justification.
- If salaried effort is not included in the budget for key study personnel, please explain.
- Sub-awards to other institutions are permissible, provided that most of the pilot project's activities and dollars spent occur within WF or one of its affiliates.

NIH-style biographical sketch for all Key Personnel

Review Criteria and Process for Full Proposals

1. An Administrative Review will be completed to verify all required components were submitted and formatting guidelines followed. **Applications that do not comply with guidelines will be automatically disqualified and will not be considered for review.**
2. Proposals that pass the Administrative Review are peer-reviewed by the WF Intramural Research Support Committee (IRSC) using NIH review criteria and scoring. Budgets will be reviewed by both Administrators and IRSC for appropriateness. There will be separate review discussions for clinical science and basic science proposals.
3. Final award approval will be at the recommendation of Wake Forest University and Wake Forest University School of Medicine Leadership.

Reviewers will score applications from 1 to 9 based on:

1. Significance of the problem to be addressed
2. Innovation of the proposed solutions
3. Strength and breadth (interdisciplinary nature) of the investigative team
4. Methodological rigor and feasibility, with clear milestones
5. Generalizability: Likelihood the innovation will be broadly applicable and impact translational research or delivery of care
6. A reporting plan, whether the study yields positive or negative results
7. The likelihood that the investment will lead to external funding, publication, 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 study participants.

Budget Guidelines

The project is one year beginning 09/01/23 and ending 08/31/24. Up to \$50,000 in direct costs may be requested.

Grant funds may be budgeted for:

- Salary support for either one or both of the two co-PIs or faculty collaborators (using NIH salary cap)
- Research support personnel (including undergraduate and graduate students)
- Travel, if necessary to perform the research
- Small equipment, research supplies, and core lab costs
- Other purposes deemed necessary for the successful execution of the proposed project

Grant funds may not be budgeted for:

- 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
- Capital equipment
- Manuscript preparation and submission
- 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 Wake Forest University, Wake Forest University School of Medicine, and Wake Forest Clinical and Translational Science Institute funds. Each entity reserves the right to revoke funding if 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).

Program Expectations

Prior to funding, awardees will be assigned to a Research Navigator to assist with study initiation and monitor progress throughout the life of the study.

Specific Deliverables

- Participation in the study initiation meeting
- A formal progress report at 6 months
- Close-out report, with plans for implementing and disseminating innovations, upon completion of the project
- Presentation of findings at requested events
- Disclosure of 1) how results will be implemented and/or disseminated; 2) applications for extramural funding beyond the pilot grant; 3) what subsequent notification of funds occurred; and 4) related publications or significant collaborations resulted from the project, for a minimum of 4 years after completion of the award.

Other Guidelines

1. Prior to receiving funds, research involving human subjects must have appropriate approval 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 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 prior to funds being released.
3. Any awardee who leaves his or her position should contact their research navigator to discuss plans for the project.

Grant Administration

The Principal Investigators are responsible for the administration of grant funds.

Contacts

Questions about your research project or the ePilot electronic submission system should be directed to Brittney Patterson at britjack@wakehealth.edu. Questions related to Reynolda campus issues should be directed to research@wfu.edu.

Appendix I: Study Milestone Examples

Below are examples of 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
- **Milestone 3 (4-6 months):** Milestone 3 Details **Outcome:** Outcome 3 Details
- **Milestone 4 (6-12 months):** Milestone 4 Details **Outcome:** Outcome 4 Details
- **Milestone 5 (8-12 months):** Milestone 5 Details **Outcome:** Outcome 5 Details

Example 2:

Timeline and Milestones												
Month	1	2	3	4	5	6	7	8	9	10	11	12
Activity/Aim/Milestone 1	X	X	X	X								
Activity/Aim/Milestone 2	X	X										
Activity/Aim/Milestone 3		X	X	X								
Activity/Aim/Milestone 4					X	X	X	X	X	X		
Activity/Aim/Milestone 5					X							
Activity/Aim/Milestone 6						X	X					
Activity/Aim/Milestone 7								X		X		
Activity/Aim/Milestone 8											X	X

Example 3:

Aim	Milestone	Month 1-3	Month 4-6	Month 7-9	Month 10-12
1	Milestone 1	X	X		
	Milestone 2		X		

Aim 1 Anticipated Outcomes: Detail

Aim	Milestone	Month 1-3	Month 4-6	Month 7-9	Month 10-12
2	Milestone 1		X	X	
	Milestone 2		X		
	Milestone 3			X	

Aim 2 Anticipated Outcomes: Detail

Aim	Milestone	Month 1-3	Month 4-6	Month 7-9	Month 10-12
3	Milestone 1			X	
	Milestone 2			X	X

Aim 3 Anticipated Outcomes: Detail

References

1. IOM (Institute of Medicine). Best care at lower cost: The path to continuously learning health care in America. Washington, DC: The National Academies Press; 2012.
2. IOM (Institute of Medicine). The CTSA program at NIH: Opportunities for advancing clinical and translational research. Washington, DC: The National Academies Press; 2013. p.36
3. IOM (Institute of Medicine). The Learning Healthcare System: Workshop Summary. Olsen L, Aisner D, McGinnis JM, eds. Washington, DC: National Academies Press; 2007.
4. NIH (National Institutes of Health) / NCATS (National Center for Advancing Transactional Sciences. Translational Science Spectrum. NCATS 2015: <https://ncats.nih.gov/translation/spectrum>