

Wake Forest Institute for Regenerative Medicine 2025 Intramural Pilot Funding Program

Purpose

The Wake Forest Institute for Regenerative Medicine (WFIRM) is an international leader in scientific discovery and its translation into clinical therapies and diagnostics. Seventeen applications of technologies developed by WFIRM scientists have been translated to patients. WFIRM applies the principles of regenerative medicine to find solutions for diagnosing and treating human diseases and disabilities. The research and development activities at WFIRM also rely on the Atrium Health and Wake Forest community's interdisciplinary expertise.

The WFIRM Intramural Pilot Funding Program promotes innovative and collaborative translational research within the Atrium Health and Wake Forest School of Medicine communities. WFIRM's pilot program encourages the integration of new technologies and expertise to team up with current research projects and develop the subsequent phases of translational research.

Up to 2 projects will be funded. Successful pilots will receive up to \$30,000 to be spent within a 12-month project period. Completed applications are due December 13, 2024 (see below).

Research Topics

Proposals should aim to lead to translation of regenerative medicine applications. Below are suggested topics, but are not limited to the following areas:

- Human and animal pre-clinical studies of disease and therapy (e.g. congenital/genetic, trauma, aging, environmental, etc.)
- Studies involving pharmacokinetic analysis (e.g., drug response of organoids, secreted compounds in body-on-a-chip systems, small molecule discovery, etc.)
- Studies involving development and application of Imaging technologies (e.g., non-invasive imaging of tissues in vivo and in vitro, high content imaging, novel imaging technologies, etc.)
- Studies involving cellular and genetic engineering (e.g., gene therapy, cell-mediated drug delivery, genetically modified cell, tissue models, etc.)
- Studies involving development and application of biomaterial technologies (e.g., smart biomaterials, cell-free biomaterials for tissue regeneration, drug-eluting biomaterials, etc.)
- Development of application-based algorithms for automation, deep learning, and artificial intelligence for regenerative medicine therapies
- Advanced manufacturing for regenerative medicine therapeutics (biomaterials, cells, genetic vectors, engineered tissues, etc.)

Eligibility

These awards are open to investigators with faculty rank across the Southeast region of Advocate Health. This includes Atrium Health, Atrium Health Navicent, and Atrium Health Wake Forest Baptist, including Wake Forest University School of Medicine.

Minimum Qualifications

- Requires the involvement of at least one WFIRM primary faculty
- Proof of research concept already established
- Team management plan

Desirable Qualifications

- Collaboration among groups
- Novel approaches to research
- Subsequent translation and funding plan included

Key Dates

Date	Detail
12/13/24, 11:59 pm EST	Full Application Deadline
02/15/25	Selection of Awardees
03/15/25	Project Start Date
03/14/26	Project End Date

Funding

The Wake Forest Institute for Regenerative Medicine will fund up to \$30,000 in direct costs per project, with funds to be dispersed in increments pending successful progress and attainment of milestones. See the section on Budget Guidelines for more details on allowable and non-allowable budget items. An ad hoc selection committee will evaluate proposals for the projects' connection with the program's objectives and meeting selection criteria. Final funding decisions will be made based on the selection committee's recommendations and the alignment to the goals of the program.

Application Procedure

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

Complete Application Deadline: 12/13/2024 by 11:59 pm

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 (500 words max)

Research Plan (4 pages max)

- *General Background*
- *Significance* – Explain how the project addresses a significant problem, how it will improve scientific knowledge, technical capability and/or clinical practice.
- *Innovation* – Explain how this project uses novel concepts, approaches or methodologies, instrumentation or interventions.
- *Approach* –
 - Specific Aims
 - Overall strategy for this project, methods including anticipated barriers or technical difficulties and potential problems, alternative approaches, and benchmarks for success.
- *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.
- *Projected Timeline* - (examples can be found in [Appendix I](#))
- *Identify if application is under submission or submitted for other Center awards*

Next Phase (1 page max)

Describe how the project will progress to translation and, if successful, sources from which further funding will be sought based on the results of this project.

- Translation plan with potential clinical and commercial outcomes
- Extramural support. Indicate opportunities for follow-on extramural support, including specific programs, and why you anticipate the research supported by this pilot grant will leverage external support. If the proposed project has previously been submitted for external support, please add a copy of the executive summary of the review from the agency it was submitted to with your application.

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**). Pre-submission discussion with the Wake Forest IRB is strongly suggested.

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 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)

Appendix information is limited to:

- A Summary Statement from the previous grant submission justifying the need for additional experiments.
- Reviewer Comments from the previous manuscript submission justifying the need for additional experiments to secure a high visibility publication.

Budget Guidelines

The budget period is for 12-months ending no later than 03/14/2026. Up to \$30,000 in direct costs may be requested.

Grant funds may be budgeted for:

- Research support personnel (including undergraduate and graduate students)
- 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 salaries
- Office supplies or communication costs, including printing
- Meals or travel, including to conferences
- Professional education or training
- Computers or audiovisual 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 WFIRM funds. WFIRM 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).

Multiple Submissions

The PI must identify whether the application is submitted to CTSI or other Wake Forest School of Medicine Centers for consideration of funding.

Review Criteria and Process

WFIRM proposals are competitive and peer reviewed. Proposals will be evaluated by 02/15/2025. Funding decisions will be made based on the reviews of an evaluation of the projects' connection with the goals of WFIRM. Final award approval will be at the recommendation of WFIRM Leadership. 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 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

Should any significant issues arise, the study team will be required to work with the WFIRM Director to define an intervention strategy for the study to be successfully completed (or in rare cases, terminated).

Specific Deliverables Include:

- Awardees will be required to submit a written progress report midyear and a final report within 60 days after completing the project. Awardees may be invited to present results at the WFIRM faculty project meeting.

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 WFIRM 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 WFIRM prior to funds being released.
3. WFIRM 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 Wake Forest Institute for Regenerative Medicine at 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 WFIRM Director 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 research project and specific information should be directed to Shay Soker at ssoker@wakehealth.edu.

Questions about the ePilot electronic submission system should be directed to Katelyn Still at kastill@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				
Quarters	1	2	3	4
Activity/Aim/Milestone 1	X	X	X	
Activity/Aim/Milestone 2	X	X		
Activity/Aim/Milestone 3		X	X	X