Wake Forest Institute for Regenerative Medicine
2023 Intramural Pilot Funding Program

The Wake Forest Institute for Regenerative Medicine (WFIRM) is an international leader in translating scientific discovery into clinical therapies and diagnostics. 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 rely heavily on the Atrium Health and Wake Forest community's interdisciplinary expertise.

Purpose
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, and the successful pilot will receive up to $30,000 funding amount, to be spent within 12 months.

Research Topics
The research proposals may include one of the following areas but are not limited to that leads to the translation application of regenerative medicine:

- Human and animal clinical models of disease and therapy (e.g. congenital/genetic, trauma, aging, environmental, etc.)
- Pharmacokinetics (e.g., drug response of organoids, secreted compounds in body-on-a-chip systems, small molecule discovery, etc.)
- Imaging (e.g., non-invasive imaging of tissues in vivo and in vitro, high content imaging, novel imaging technologies, etc.)
- Cellular and genetic engineering (e.g., gene therapy, cell-mediated drug delivery, genetically modified cell, tissue models, etc.)
- Biomaterial technologies (e.g., smart biomaterials, cell-free biomaterials for tissue regeneration, drug-eluting biomaterials, etc.)
- Mathematical modeling (e.g., effects of media components on cell growth, response of organoids to external factors, tissue regeneration models, etc.)
- Development of application-based algorithms for automation, deep learning, and artificial intelligence for regenerative medicine therapies

For inquiries and specific information, please contact Shay Soker at ssoker@wakehealth.edu

Eligibility
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
12/14/22, 11:59 pm	Full Application Deadline
02/15/23	Selection of Awardees
03/15/23	Project Start Date
03/14/24	Latest Project End Date

Funding

WFIRM 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 by the Institute Director based on the selection committee's recommendations.

Application Procedure
Full Application Deadline: 12/14/22, 11:59 pm
The application can be submitted 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 (500 words max)

Research Plan (4 pages max)
- *General background*
- *Significance* – Explain how the project addresses a significant problem and 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* –
  o Specific Aims
  o 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 team member will contribute to the project. Include their expertise and experience that will be utilized on this project.
- *Projected Timeline*

Next Phase (Limit 1 page)

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. Suppose this project has previously been submitted for external support. In that case, a copy of the executive summary of the review from the agency it was submitted to should be included 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 <u>not required</u> 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, if applicable.
- 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 budget template form and 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 03/14/2024. 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 using WFIRM funds. The WFIRM leadership reserves the right to revoke funding if it is determined that funds were not spent per the approved protocol. The general criteria for determining allowable direct costs on federally sponsored projects are outlined in 2 CFR Part 200: Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards (The Uniform Guidance).

Review Criteria and Process
Proposals will be evaluated by 02/15/2023. 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 an impact on the translation applications of regenerative medicine, 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 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. 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 Name before funds are 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 before starting the grant period.
2. It is expected the PI will report outcomes achieved due to the pilot award, e.g., subsequent external funding, publications, presentations, and patents.
3. Any awardee who leaves their position should contact 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 12 months.

Contacts
Shay Soker at ssoker@wakehealth.edu

Questions about your research project or the ePilot electronic submission system should be directed to Michael Skidmore, mwskidmo@wakehealth.edu.