

Wake Forest School of Medicine

The Academic Core of Atrium Health

Translational Research Initiative - Joint Pilot Application Guidelines

Purpose

As the Academic Core of the new Atrium Health, the Wake Forest School of Medicine is seeking applications for translational research projects. The primary focus of this Request for Applications (RFA) is to encourage the development of interdisciplinary research teams for translational research involving collaborators across the new Atrium Health Enterprise. The new Atrium Health Enterprise is the result of the strategic combination of Atrium Health and Wake Forest Baptist Health, including the Wake Forest School of Medicine.

Collaborations may be formed by expanding existing interdisciplinary teams or establishing new teams to carry out a proposed project. Applications must include investigators from multiple Regions and Markets (e.g. one investigator from Charlotte and one from Winston-Salem). 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 and will be considered responsive. 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 six projects will be funded and will receive up to \$40,000 in direct costs. All projects must meet the specifications outlined above. All funds are to be spent within a one-year project period.

Eligibility

These awards are open to all investigators across the Atrium Health Enterprise including Atrium Health, Atrium Health Navicent, and Wake Forest Baptist Health, including Wake Forest School of Medicine. Wake Forest University faculty are also invited to apply. Applications must include investigators from multiple Regions and Markets (e.g. one investigator from Charlotte and one from Winston-Salem). Interdisciplinary teams that represent combinations of clinicians and basic scientists; adult and pediatric researchers; and/or junior and senior investigators are all strongly encouraged to apply.

Additional Information:

More than one proposal may be submitted per faculty member serving as PI or co-PI, but the faculty member is only eligible to receive one award as either PI or co-PI during a given funding cycle.

Key Dates

Date	Detail
01/11/21, 11:59 pm	Letter of Intent (LOI) Deadline
02/02/21	Investigators Invited for Full Application
03/03/21, 11:59 pm	Full Application Deadline
04/14/21	Selection of Awardees
06/01/21	Project Start Date
05/31/22	Project End Date

Resources Available to Support Investigators

The Wake Forest CTSI supports resources to help strengthen applications; while they are not required as part of the submission, investigators are encouraged to seek 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. The editor 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 virtually with a statistician to develop your study design, measurement, and statistical analysis plans prior to submission (free to everyone).

Application Procedure

1. Letter of Intent Deadline: 01/11/21, 11:59 pm

Letters of Intent (LOI) (2 pages max) require the following:

- A brief abstract, including specific aims
- A clear statement of how the project will overcome translational barriers
- A list of study team members for the proposed project including roles and home institution
- References are not included in the 2 page limit

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

Review Criteria and Process for Letters of Intent

1. An Administrative Review will be completed to verify all required components were submitted and formatting guidelines followed (e.g., does not exceed page limit).
2. Letters of Intent that pass an administrative review will then be reviewed by a multidisciplinary team from Legacy Wake Forest and Atrium. Reviewers will be evaluating whether proposed projects can help catalyze translation and will determine if the project is responsive to the RFA.
3. After this review, teams will receive notice that they are being invited to submit a full application or that they were not selected for this round via e-mail by **02/02/21**.

2. Full Application Deadline: 03/03/21, 11:59 pm

Investigators invited to apply will receive an e-mail by 02/02/21 with a link to submit a full application **by 03/03/21**. **Applications received after 03/03/21 will not be reviewed.** 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 Principal Investigator, 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

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)
- Clinical Trial Classification Questions
- 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 Plans for Women, Minorities, and Children, if applicable

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.
- 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 will be peer reviewed by a team of scientists from Legacy Wake Forest and Atrium using NIH review criteria and scoring. Budgets will be reviewed for appropriateness.
3. Final award approval will be at the recommendation of the Strategic Combination Research Executive Committee on behalf of the Chief Academic Officer's Office.

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 06/01/21 and ending 05/31/22. Up to \$40,000 in direct costs may be requested.

Grant funds may be budgeted for:

- Salary support for the PI 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. Leadership reserves the right to revoke funding if it is determined that funds were not spent in accordance with the approved protocol.

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 appropriate IRB(s). 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 institutions’ 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 during the course of the award should contact administration to discuss plans for the project.

Grant Administration

The Principal Investigator is responsible for the administration of grant funds.

Contacts

Questions about your research project or the ePilot electronic submission system should be directed to Lindsay Trost at ltrost@wakehealth.edu.