



Catalyst Fund – Intermediate Awards Program

Application deadline, Dec 3rd, 2020

**Project start date for awardees is no earlier than
Feb 1st, 2021**

Interested applicants are encouraged to seek pre-submission consultations with Wake Forest Innovations (see contact information and links below). Consultations should be scheduled at least two weeks in advance of the submission deadline.

Background

The Catalyst Fund was established to help advance Medical Center faculty inventions with bona fide clinical and commercial potential towards translational milestones where they can attract private sector investment and be successfully licensed to either an existing or a new start-up company to complete their development and commercialization. Any life science-related faculty invention is an eligible candidate technology.

The Fund is managed by an independent Program Manager in conjunction with Wake Forest Innovations and an advisory Steering Committee that includes external experts. Catalyst project support includes funding, expert advice, and networking. Program participation entails a modification of the distribution of future licensing revenues generated by participating technologies, with a portion going back into the Fund.

In 2018 Catalyst created Intermediate Awards, a new funding category intended to provide relatively small amounts of capital to a greater number of faculty inventors and thereby fill the gap between WFI's Commercial Pathway Awards and Catalyst's larger project commitments. Intermediate Awards go through a simplified application and review process. Applications are screened by WFI and reviewed and scored by the Catalyst Steering Committee based on their translational merit, with the objective of accepting up to 5 – 10 projects over the course of the coming year.

Intermediate Awards Overview

Purpose: The Intermediate Awards program aims to advance the development of faculty inventions that have significant potential to become innovative new medical products that positively affect clinical practice and patient outcomes, and that therefore also have the potential to attract future licensing and investor interest to support commercialization. Intermediate Awards, like other forms of funding support overseen by Catalyst, are aimed strengthening the entrepreneurial culture within the Medical Center.

IA funding supports experimental studies that explore potential commercial applications of early-stage life science inventions and enable "go/no-go" decision-making regarding further development and/or pursuit of intellectual property protection. This funding is intended to enable faculty inventors to apply commercialization criteria in exploring potential scientific and product development applications of inventions that are ready to transition out of basic research into the early product development phase.

Range of funding: \$50,000 - \$100,000

Catalyst project funding is exempt from the normal indirect cost allocation, since it is provided almost entirely in-house. A portion of future licensing revenues is required to be paid to Catalyst, though unlike other Catalyst funding programs, such distributions are capped at 2.5x the amount of the Intermediate Award.

Application dates: twice a year, roughly aligned with the CTSI application and Catalyst Steering Committee timetable.

Eligibility: any life science-related invention by a faculty member or clinician that has the potential to be developed and commercialized as a clinical intervention in patient care; maximum one-year project timeframe. Project proposals must be translational in nature.

Application Procedure

No Letter of Intent or notice in advance of the final application deadline is required. However, interested faculty members are encouraged to seek pre-submission consultations with Wake Forest Innovations (see contact information and links below). Consultations should be scheduled at least two weeks in advance of the application deadline.

Application Deadline: December 3rd 2020, 11:59 pm

Faculty investigators are invited to submit a full application by December 3rd, 2020 through the <https://redcap.wakehealth.edu/redcap/surveys/?s=FP7PAAK447>. The 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 Plan (4 pages max, all items below are required components of the research plan)

- Specific Aims (1 page max)
- Background and Significance, translational importance, experimental design and methods, dissemination and implementation plan (1 page max)
- Study milestones and anticipated outcomes with timeline (1 page max)
- Contribution and summary of qualifications of each contributing investigator (1 page max)

References (2 page limit)

Information Regarding Live Vertebrates

- IACUC Approval Status if the project **involves live vertebrates** (IACUC approval is not required for full application submission)

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 there are any external collaborators and 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 (new style)

Budget Guidelines

The project timeframe is one year beginning on the effective date of the related Catalyst Fund project documents. The project documents include an Investigator Memorandum of Understanding that governs the distribution of any future licensing revenues generated by the technology. Such licensing revenues go first to paying back the amount of the Intermediate Award and patenting costs, and thereafter are distributed 80:20 between the WFUHS IP policy and the Catalyst Fund, up to a maximum of 1.5x the amount of the Intermediate Award. After the 1.5x ceiling is reached, licensing revenues are distributed according to the WFUHS IP policy.

From \$50,000 up to \$100,000 in direct costs may be requested. Catalyst Intermediate Awards are not subject to indirect cost allocations.

Project funds may be budgeted for:

- Salary support for the WFUHS PI or WFUHS faculty collaborators (using NIH salary cap)
- Research support personnel (including undergraduate and graduate students)
- Salary support should not exceed more than 30% of the total budget
- Small equipment, research supplies, and core lab costs
- Other purposes deemed necessary for the successful execution of the proposed project

Project 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
- Capital equipment
- Manuscript preparation and submission
- Indirect costs

Awarded funds must be used to conduct the work proposed. Catalyst reserves the right to revoke funding if it is determined that funds have not been spent in accordance with the approved protocol.

Review Criteria and Process

Catalyst Intermediate Award proposals are reviewed by the Catalyst Steering Committee, which consists of selected external experts as well as Medical Center faculty and WFI staff under the leadership of an independent Program Manager. Final award approval will be

on the recommendation of the Steering Committee and at the discretion of the Program Manager. WFI will notify applicants regarding the outcome of the project review process.

Reviewers will score applications from 1 to 5 based on:

1. Significance of the problem to be addressed
2. Innovation of the proposed solution and potential impact on the problem
3. Strength of the existing or prospective IP position
4. Strength and breadth of the investigative team
5. Methodological rigor and feasibility of the project proposal, with clear milestones
6. Feasibility that the innovation can ultimately be partnered, developed and commercialized, reflecting its potential clinical and commercial utility and value

Numerical scoring is used as an indicative input to the evaluation process. There is no set level that serves as an automatic fundable threshold, nor any forced ranking by score; each proposal is evaluated on its own merits.

Program Expectations

Prior to funding, awardees will be assigned to a WFI case manager to: 1) assist with completion of Catalyst project documents and study initiation; and 2) monitor progress throughout the course of the study. If any significant issues arise, the study team will be required to work with WFI and Catalyst to determine solutions so that the study can be successfully completed (or in rare cases, terminated).

Specific Deliverables

- Participation in WFI study initiation meetings
- Regular interactions with the WFI case manager to monitor progress
- Upon completion of the project:
 - Close-out report, with plans for implementing and disseminating innovations
- Presentation of findings to the Steering Committee and at other requested events
- Disclosure of 1) how results will be implemented and/or disseminated; 2) applications for extramural funding; 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.

Contacts:

Deepika Poranki, PhD, Associate Director, Wake Forest Innovations

336.716.4411 office

dporanki@wakehealth.edu

Catalyst Intermediate Award Application Template

Project Title:

Inventor/Investigator(s)

Name:

Title:

Department:

Telephone:

Email:

Category:

☐ Therapeutic/drug/biologic

☐ Diagnostic

☐ Medical device

☐ Digital health

☐ Precision Medicine

☐ Other (please describe)

Intellectual property status:

Project abstract:

Existing collaborations, partnerships and funding:

Target indication/disease:

Current standard of care and unmet need (include existing products and competitors you are aware of:

Proposed product's target characteristics and competitive advantages:

Any indicative information on market size and potential and thoughts on downstream development and commercialization you may have:

Competitive research you may be aware of that represents a likely alternative solution:

Any investor or industry interest, contacts or relationships:

Project proposal:

Budget (\$50,000-\$100,000):