Wake Forest™
Innovations

COMMERCIALIZATION PATHWAY AWARD

Application deadline – December 24th 2022

Project start date for awardees is no earlier than January 31st, 2023

Interested applicants are welcome 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.

Purpose

The mission of Wake Forest Innovations is to translate research into beneficial products and services.

The Commercialization Pathway Award furthers this mission by supporting members of the Wake Forest community by awarding financial support for <u>milestone-driven commercially relevant projects in which the institution has a proprietary position.</u> Projects should be designed to advance the licensability and commercial potential of technologies and intellectual property. Examples of suitable projects include advanced proof-of-concept and feasibility studies, studies that enable go/no-go commercialization decisions, and studies designed to exceed commercially relevant value inflection points.

Application Deadline: December 24th 2022, 11:59 pm

Researchers are invited to submit a full application by December 24th, 2022 through the https://redcap.wakehealth.edu/redcap/surveys/?s=7874R98Y9YMFDWC4. The instructions are summarized below.

Successful projects will receive up to $40,000 in direct costs.

Applications should fall into one of the following areas:

<u>Category:</u>
☐ Therapeutic/drug/biologic
☐ Diagnostic/Medical device
☐ Digital health
☐ Other (please describe)

Project final budgets will be based on a complete review of the budget and budget justification. See "Budget Guidelines" below for more details. All funds are to be spent within a one-year project period. No-cost extensions may be approved in exceptional circumstances for no more than 6 months.

Eligibility

These awards are open to all employees from Wake Forest School of Medicine, Wake Forest University, Atrium Health - Wake Forest Baptist as well as Atrium Health employees with Wake Forest appointments.

Proposals

General Proposal Formatting Guidelines:

- Use standard font (such as Times New Roman or Arial) no smaller than 11 point.
- Page set-up should be for single-spacing on 8½"x11" paper.
- Consecutively numbered pages.
- Margins should be at least 0.5" (sides, top and bottom)
- Each section should be titled using the header sections listed below and should match the Table of Contents.
- Do not use logos or letterhead on any pages of the Proposal except for support letters.

- Judicious use of headings and white space for ease of reading is appreciated.
- **Cover Page**
  - Total funding requested
  - Project Title
  - Principal Investigator (PI) or Co-Principal Investigators (Co-PIs): name, degree, rank or job title, primary departmental affiliation
  - Any additional key project team members: name, degree, rank or job title, primary departmental affiliation, and institutional affiliation for any external collaborations
  - WFI case number – if already disclosed
  - Abstract in lay language (150 word limit)
- **Proposal body**
  - 4 page limit for Sections 1-4, including Figures & Tables

  The following sections should appear in order:

1. **Problem**
   ### 1.1. Unmet Need
   Clearly define and express the magnitude of the specific marketplace need addressed by your invention / innovation, and the current players and competitors.

   ### 1.2. Technical Problem
   Clearly define the technical problem(s) / hurdle(s) that your invention / innovation overcomes.

2. **Solution**
   ### 2.1. Product Concept
   Describe your overall product concept (e.g. therapeutic, diagnostic, or device product, consumer product or service; stand-alone product or used in combination with existing product(s), etc.).

   ### 2.2. Rationale
   Present the rationale for the invention / innovation. Focus on the unique merits of the invention that distinguish it from what currently exists.

   ### 2.3. Progress to Date
   State your progress to date on the invention. Include preliminary data.

3. **Project plan**
   ### 3.1. Milestones

State the specific milestone(s) to be achieved with project funding. Milestones provide a clear roadmap for your project. A milestone marks the completion of a major deliverable, and is specific, measurable and attainable. A milestone usually refers to a deliverable that marks the transition of a project from one phase to another – for example, identification of a set of hit or lead compounds against a drug target (see Figure 1).
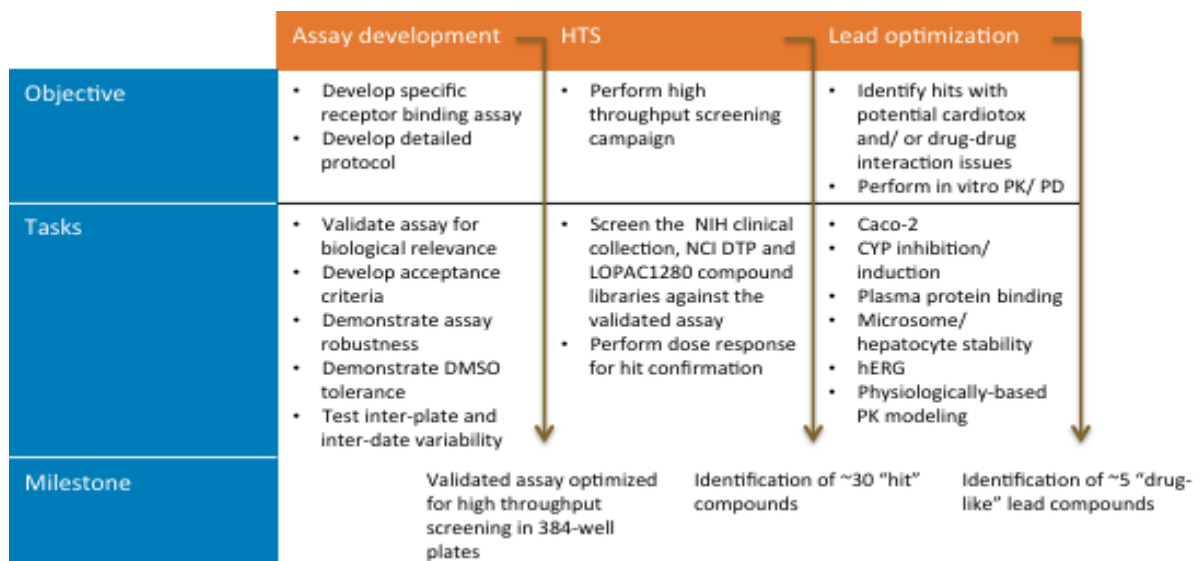
	Assay development	HTS	Lead optimization
Objective	• Develop specific receptor binding assay • Develop detailed protocol	• Perform high throughput screening campaign	• Identify hits with potential cardiotox and/ or drug-drug interaction issues • Perform in vitro PK/ PD
Tasks	• Validate assay for biological relevance • Develop acceptance criteria • Demonstrate assay robustness • Demonstrate DMSO tolerance • Test inter-plate and inter-date variability	• Screen the NIH clinical collection, NCI DTP and LOPAC1280 compound libraries against the validated assay • Perform dose response for hit confirmation	• Caco-2 • CYP inhibition/ induction • Plasma protein binding • Microsome/ hepatocyte stability • hERG • Physiologically-based PK modeling
Milestone		Validated assay optimized for high throughput screening in 384-well plates	Identification of ~30 "hit" compounds	Identification of ~5 "drug-like" lead compounds

Figure 1. Example of relationship between milestones, objectives and tasks. Milestones are specific and measurable, and mark the completion of a deliverable: they often consist of a number of related objectives. Objectives describe what has to be done to reach the milestone. Tasks describe how the objectives will be achieved.

3.2. Plan

Explain how the Milestones will be achieved. Include a timeline (see template).

3.3. Translation / Commercialization Impact

Describe how success in achieving the Milestone(s) will advance translation and commercialization of the innovation / invention.

4. Evaluation

4.1. Go/no-go criteria

Define the criteria for a go/no-go decision-making. Include defined metrics that will indicate or demonstrate a successful outcome (see Figure 2).

Milestone	Go Decision	Associated Metric
Validated assay optimized for high throughput screening	1. Assay compatible with HTS 2. Acceptable Z- factor	1. Robust results in 384 or 1536 well plates 2. Ideally >0.5

Confirmation of Hits	1. Adheres to Lipinski rules	1. < 5 hydrogen bond donors, < 500MW, logP < 5
	2. Demonstrates growth inhibition in at least 1 primary cell line	2 < 250nM concentration and rational SAR established for the series
Selection of Leads	1. Low potential for drug-drug interaction	1. CYP450 IC50 between 1µM - 10µM = moderate inhibition (OK), IC50>10µM (ideal)
	2. IP position is exclusive with full freedom to operate	2. No concerning prior art identified during initial survey

Figure 2. Example go/no-go decision metrics which advance the project from milestone to milestone. There may be one or many go/no-go decisions points to be considered before advancing to the next milestone

5. **Budget** (no page limit)

5.1. Budget justification

A detailed budget justification which tracks to the project plan is required. Specify and justify any unusual materials or services, capital equipment, animal costs (IACUC approval required), or human studies (IRB approval required).

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 organizations are permissible, provided that work is performed on a work for hire basis.

Awarded funds must be used to conduct the work proposed.

5.2. Budget template

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.

Show major categories (e.g., Personnel, Animals, Consumables, Consulting, Contract Research).

- List all personnel. Salary support should not exceed more than 10% of the total budget. The 10% cannot be credited towards the investigator's match with institutional funds.

Attendance at scientific conferences, publication costs, and similar expenses should not be included.

Commercialization Pathway Award funds may **not** be budgeted for:
- Office supplies or communication costs, including printing
- 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

6. **Information Regarding Live Vertebrates**
   Address the following if the project **involves live vertebrates**.
   - IACUC Approval Status (please note: IACUC approval is <u>not required</u> for full application submission)

7. **Intellectual Property (IP)** (<u>no page limit</u>)

   Describe the status of IP protection and how this proposal fits with the project's IP and commercialization strategy. Briefly describe current solution and competitive landscape.

8. **References cited** (<u>no page limit</u>)

   Please use a format that includes article title and names of first author and last author (i.e., generally the laboratory head)

9. **Biosketches**

   Biosketch of PI or Co-PIs and any key team members and collaborators (NIH format, new style, <u>1 page limit</u> per investigator. Please limit publications to 5 key)

10. **Collaboration letters for any external institutions or companies, if relevant** (<u>no page limit</u>)

Review Process

A review committee guided by Wake Forest Innovations personnel will make final funding decisions.

Award Management

Each project team will work closely with a member Wake Forest Innovations to track progress towards Milestones and modify activities if necessary. Projects should be completed within 1 year of award date.

Specific Deliverables
- Quarterly reports (template provided to awardees) to the WFI case manager
- Upon completion of the project:
  - Close-out report
  - Disclosure of 1) applications for extramural funding and subsequent notification of funding; and 2) related publications or significant collaborations

Contacts:

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