NCAI-CC NIH Center for Accelerated Innovations at Cleveland Clinic

TECHNOLOGY DEVELOPMENT PROGRAM

SPECIAL REQUEST FOR APPLICATIONS ■ DECEMBER 2017 (ROUND 9)

SPECIAL FUNDING OPPORTUNITY

The goal of this special funding opportunity is to identify, select, and advance qualified projects in special areas of clinical interest identified by the National Heart, Lung and Blood Institute (NHLBI), specifically:

- Chronic Obstructive Pulmonary Disease
- Idiopathic Pulmonary Fibrosis
- Pulmonary Hypertension
- Heart Failure
- Myocardial Infarction
- Non-statin Lipid Lowering Drugs
- Sickle Cell Anemia

This funding opportunity is open to diagnostic assays, tests or systems; interventional, surgical, or therapeutic devices; therapeutic pharmaceutical, biologic, or regenerative medicine product solutions.

PRE–QUALIFICATION

Candidate projects must be discussed with and pre-approved by NCAI-CC product development directors and home institution technology commercialization office representatives prior to submission.

KEY DATES

- Request for Applications released – **December 15, 2017.**
- Full project applications due – **January 24, 2018**.
- Award notices – **April 2018**.

This RFA, appendices and forms are available for download at www.ncai-cc.ccf.org Technology Development.

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For further information Contact:
Email: NCAICC@ccf.org
Telephone: 216-444-5322

TECHNOLOGY DEVELOPMENT PROGRAM

SPECIAL TARGETED RFA ■ DECEMBER 2017

1. NIH Center for Accelerated Innovations

1.1. Purpose

The National Institutes of Health has launched a major initiative to improve how basic science discoveries and new technologies are translated into commercially viable products that improve patient care and advance public health.

The NIH Centers for Accelerated Innovations (NCAI) program, funded by NIH's National Heart, Lung, and Blood Institute (NHLBI), targets technologies to improve the prevention, diagnosis, treatment, and management of heart, lung, blood, and sleep disorders.

According to NHLBI's Fact Book for the 2012 fiscal year, the estimated economic cost for cardiovascular, lung, and blood diseases was $424 billion — 23 percent of the total economic costs of illness, injuries, and death in the United States. In addition, cardiovascular and lung diseases accounted for three of the four leading causes of death in the United States and four of the 10 leading causes of infant death.

NCAIs will provide an integrated, systematic, and comprehensive approach to navigating the translation of early stage biomedical innovations from the research laboratory to commercial development and successful deployment to patients. Three inaugural NCAIs have been established, including the NCAI-Cleveland Clinic.

1.2. Center Organization and Goals

The NCAI led by Cleveland Clinic (NCAI-CC) is a multi-institutional consortium of leading clinical and academic institutions including Case Western Reserve University, The Ohio State University, the University of Cincinnati, Cincinnati Children's Hospital Medical Center, the University of Michigan, and Northwestern University. The Center was established in 2013 with $11 million in grant funding from NHLBI plus subsequent supplements and complemented with a $1.5 million grant from the Ohio Third Frontier program.

In addition, each participating institution has committed matching funds to each project selected for funding from that institution.

The goals for the NCAI-CC program are:

1. To advance development of commercially-promising projects related to the prevention, diagnosis, treatment and management of cardiovascular, lung, blood and sleep disorders involving projects which span the technology range of diagnostics, diagnostic systems, devices, therapeutics and tools.

2. To select, fund, and guide projects through a process of rigorous peer-review, emphasis on commercialization criteria in project planning, and milestone-driven project management.

3. To organize new and existing resources into a broadly accessible community for educating and mentoring researchers, clinicians and developers in the processes of biomedical innovation, entrepreneurism, and commercialization.

2. Program Description

2.1. Overview

The NCAI-CC Technology Development Program is targeted to assist the validation and advancement of early stage technologies to establish commercial product potential.

The program operates under a periodic Request for Applications (RFA) basis to solicit projects from NCAI-CC partner institutions for funding and project support. Funds under the program are allocated to specific, measurable project development activities that are key to establishing commercial opportunity. Project scope typically encompasses work which leads to achieving critical project milestones that can be accomplished within a period of one year, and which serve to enable follow-on funding from later stage investment sources such as other federal programs (e.g., SMARTT, SBIR/STTR), other state programs (e.g. Ohio Third Frontier, Global Cardiovascular Innovation Center), venture capital or industry.

NCAI-CC has formed an independent External Selection Committee comprised of prominent clinicians, scientists, industry representatives, business development experts, and members of the venture capital community. The ESC provides clinical, technical and commercial evaluation and guidance to the selection of projects for funding.

NCAI-CC staff includes industry-experienced project directors and developers who will work closely with each selected project to provide commercial assessment, project guidance and access to resources to help in project planning and successful achievement of project milestones.

2.2. Eligibility

Applications are accepted from investigators at NCAI partner institutions Cleveland Clinic, Case Western Reserve University, The Ohio State University, the University of Cincinnati, Cincinnati Children's Hospital Medical Center, the University of Michigan, and Northwestern University.

The NCAI technology development program encompasses and seeks a broad portfolio of NHLBI-related projects directed to the prevention, diagnosis, and treatment of cardiovascular, lung, blood, and sleep disorders spanning the technology range of diagnostics, diagnostic systems, devices, therapeutics, and tools.

Please contact NCAI-CC for clarification if you are unsure if your project falls within the NCAI domain.

Applications submitted should be for projects directed towards achievement of critical development milestones with the objective of advancing the technology towards commercialization. Use of NCAI funds should be directly allocated to specific, measurable project activities that are key to establishing commercial opportunity, and on a timeline covering a period of approximately one year from grant of the award.

Note: for therapeutics development projects, it is strongly recommended that you have a lead compound identified with disease target validated by appropriate screening assays along with initial indication of efficacy in-vivo in order for the project to be considered at an appropriate stage for program funding. If there is question regarding project stage or readiness, please contact program personnel.

2.3. General Evaluation Criteria

Applications will be evaluated based on the following general criteria:

A. Fit with NHLBI mission, domain and NCAI program.

- Projects directed towards development of diagnostics, devices, therapeutics or tools in clinical application areas directly related to cardiovascular, lung, blood or sleep disorders.

B. Commercialization Focus and Opportunity

- Clinical significance
- Market opportunity
- Commercial value proposition
- Innovation and novelty
- Competitive advantage
- Intellectual property protection
- Regulatory pathway
- Third party reimbursement and payment

C. Project Plan

- Project definition
- Specific project goals and milestones for which award funding will be used
- Research and development to-date
- Development timeline
- Development cost and strategy for follow-on funding
- Budget
- Project team

More detailed technology review criteria are provided in Section 4.

2.4. Funding Awards

A total of up to $150,000 in direct cost budget may be made available per project, comprised of up to $75,000 in federal funds from the NCAI program plus an equal amount in required non-federal matching funds (ratio of $1 to $1). Funding awards will be in the form of a grant.

Matching Funds Requirement. One half of the total direct costs budget must be supplied by non-federal funds. The matching funds are intended to be provided through an applicant institution-managed funding source. The matching funds source must be identified at time of application and funds available to be applied to direct project costs in parallel with the federal funds during the project period.

Indirect Costs. In addition to the federal funds for the direct cost budget, NCAI will provide F&A costs (indirects) in an amount equal to the federal share of the direct funding multiplied by the applicant's institution federally approved rate.

2.5. Engagement and Reporting Requirements

Engagement by the institution's Technology Commercialization Office in support of the project is required.

NCAI project directors will be assigned to work with awardees to assist in planning and guiding project objectives, milestones, and progress. The project directors will engage in regular and frequent project reviews with awardees. Project funding is contingent on achieving progress towards meeting stated project milestones. Invoices will be required to document appropriate expenditure of funds.

Upon completion of the project period, submission of a final report will be required. Progress updates will be required on an ongoing basis during and after the project period to facilitate tracking technology development.

All updates and reports will be submitted in the form and format required by NCAI.

3. Program Process

The program process consists of the following steps:

1. Release of RFA.
2. Pre-qualification discussion.
3. Full application submission and review.
4. Funding decision and award implementation.
5. Project execution and management.
6. Follow-on progress reports.

3.1. RFA Release

Requests for Applications (RFA) under the Technology Development Program are issued on a periodic basis, usually twice per year, and communicated broadly among the Center's partner institutions.

This RFA and associated forms are publically available for download at www.ncai-cc.ccf.org - Technology Development. See cover page of this document for specific dates pertaining to the current funding round.

3.2. Pre-qualification Discussion.

In lieu of a letter of intent which is required in NCAI-CC general funding rounds, this special targeted funding round requires that PIs have a pre-qualification discussion with a NCAI-CC product development director to qualify the project for application. The discussion will confirm fit with the clinical areas of interest targeted in this special funding opportunity and appropriate stage of project development.

Contact Information:

For devices, imaging, or other "hardware/software" based projects, please contact: Marwane Berrada. berradm@ccf.org. 216-444-6898.

For diagnostic assay or test, pharmaceutical, biological, or regenerative medicine development projects, please contact: Suguna Rachakonda. rachaks@ccf.org. 216-445-3562.

Or for general inquiries, contact: NCAICC@ccf.org. 216-444-5322.

3.3. Full Application Submission and Review

Applicants are strongly urged to engage with their local technology transfer/commercialization office, NCAI site representatives and NCAI staff during development of the full application, particularly with regard to developing the intellectual property and commercialization strategy for the project.

Upon submission, applications are subject to an initial review during which compliance with the criteria and requirements of this RFA will be assessed.

Applications that do not to meet the RFA requirements may not be reviewed further.

Applications will be reviewed by NCAI-CC and partner institution personnel and by an External Selection Committee (ESC). The process may include making an oral presentation to or having discussions with the selection committee.

Applications selected as finalists from the ESC review will then be reviewed by the NHLBI NCAI Program Technology Review Committee (TRC). The NHLBI TRC review is a final step which includes review and feedback by representatives of NIH, FDA, U.S. Patent and Trademark Office, Center for Medicare and Medicaid Services, and healthcare system personnel.

3.4. Funding Decision and Award Implementation

Funding decisions will be communicated via notice of grant award. Funding awards will be provided 50% from NCAI funds and 50% from institution cost share. Award management will be conducted under terms of a subgrant agreement in the case of funding awards to partner institutions, or a letter of commitment in the case of awards made to Cleveland Clinic investigators. In either case, the agreement will specify terms of funds distribution, providing of cost share, and methods for funds disbursement.

A documentation packet consisting of instructions, forms and agreement guidelines will accompany notice of an award.

3.5. Project Execution and Management

Experienced NCAI-CC project directors will collaborate with investigators to develop milestone driven, commercially relevant project plans, and will engage throughout the project to provide guidance and support to the project as needed. Progress will be reviewed and managed using commercial project management processes and methodologies (e.g. phase gate process) to facilitate and accelerate achievement of project milestones. Continued funding of projects will be based on demonstrated progress and successful achievement of the defined project milestones.

3.6. Follow on Progress Reports

After completion of the NCAI-funded project activities, awardees will be required to provide a final project report and follow-on status reports in order to facilitate measurement of continued project development and progress towards commercialization endpoints.

4. Proposal Requirements

4.1. General Instructions

- Invited applications must be received by NCAI-CC by the appropriate dates and times indicated on the cover page of this RFA.
- Margins must not be less than 0.75 inches on all sides.
- Font must be Arial, Helvetica, Palatino Linotype, or Georgia typeface, 11 points or larger, black.
- All pages must be numbered. The institution name and project title must appear in the footer of each page.
- The order of the sections should follow the order they are presented in Section 4.2 of this RFA. The Application Cover Page shall be the first page of the application.
- Only electronic submissions will be accepted. The proposal will be submitted via upload to the NCAI-CC website, or as otherwise instructed. Specific instructions will be provided at the time of invitation to submit full applications.

4.2. Application Contents

Applications must include the following contents:

- Application Cover Page
- Executive Summary
- Project Description
  1. Background
  2. Unmet Need
  3. Proposed Product/Solution
  4. Market Opportunity
  5. Competitive Landscape
  6. Intellectual Property
  7. Product Value Proposition
  8. Clinical and Regulatory Path
  9. Payment and Reimbursement Path
  10. Project Plan and Milestones
  11. Personnel
  12. Budget and Funding Requirements
  13. Potential Risks/Mitigation
- Appendices
  - Budget Forms
  - Biosketches
  - References
  - Supplemental Information Form

4.2.1. Application Cover Page

The Application Cover Page is an information sheet that includes project title, a brief project description, and basic contact information. A copy of the form is appended to his document for reference. Forms for information entry and submission are available on the NCAI-CC website.

4.2.2. Executive Summary (Limit 1 page)

The executive summary shall consist of an abstract defining the proposed project, describing the commercial rationale and opportunity, and detailing the goals to be achieved with the proceeds of the requested funding.

4.2.3. Project Description (Limit 8 pages)

4.2.3.1. Background (2 pages maximum)

This section should include a statement of the problem addressed by the proposed project, a discussion of the scientific and clinical rationale, and the research/development accomplished to-date.

Reviewers will be considering the following questions:

- Has sufficient background been provided to help evaluate the need and the solution?
- What is the market "space" in which this product would operate?
- What is the current standard of care?
- Is the proposed project directed towards development and commercialization goals as opposed to a continuation of research aims?

4.2.3.2. Unmet Need

Projects must address a significant unmet need in the prevention, diagnosis, treatment, or management of an NHLBI-relevant disease state.

Review criteria include:

- Has the need been clearly stated?
- Has evidence of the need been provided?

4.2.3.3. Proposed Product/Solution

A clear and succinct definition of the proposed product/solution should be provided. The product/solution definition should be supported by the following information.

- What is the proposed product/solution? In which category below does it fit?
  - diagnostic assay
  - biomarker
  - diagnostic system
  - device
  - small molecule drug
  - biology drug/therapy
  - therapeutic
  - combination product
  - monitoring product/system
  - healthcare information/mHealth product

- What is the clinical application area? In which category below does it fit?
  - Heart, cardiovascular
  - Lung, airway, pulmonary
  - Blood disease or condition (non-cancer)
  - Sleep disorder.

- To what patient subset is this applicable?
- What is the expected benefit with this product/solution, and what is the evidence to support the expected benefit?
- Is the benefit a major advance or incremental in the area of speed, size, cost-saving, ease of use, safety, efficacy, accuracy or combination of areas?
- How would use of the product/solution fit with current physician practice / standard of care?

4.2.3.4. Market Opportunity

Describe the specific market segment that is addressed, including:

- What is the specific target patient population and market size that can be addressed with the product/solution? Number of patients? Number of procedures? U.S. and worldwide?
- What is the expected pricing of the product/solution? How can it be justified relative to other solutions (comparable, cost saving, value/price trade-offs)?

4.2.3.5. Competitive Landscape

Describe current and anticipated competitors in the space.

- What competitive products are in the market?
- What other competitive products are in development or anticipated to be introduced?
- What are the adjacent spaces and substitution options?
- How is the landscape shifting or projected to shift?

4.2.3.6. Intellectual Property

Describe Intellectual Property (IP) related to the technology that has been disclosed and protected.

Relevant questions that will be assessed by reviewers include:

- What does the IP cover and how is it directly related to the technology being developed?
- Have patent applications been filed? If so, please provide:
  a) Patent application number, issued patent number, trademark registration number, copyright number, etc.
  b) Title, status and date
  c) Major types of claims.

4.2.3.7. Product Value Proposition

Describe the key quantifiable advantages and benefits expected that will set your product apart from the standard of care and competition, including:

- How the product/solution will lower cost, increase productivity, and provide better outcomes than others that are currently in use.
- How the product/solution is better than what is expected to come to the market.
- What data needs to be generated to support/validate the differentiation?

4.2.3.8. Clinical and Regulatory Path

Describe the likely clinical and regulatory requirements for marketing the product, including:

- What will be the expected intended use or indication for use statement?
- What is the expected regulatory pathway?
- What safety or efficacy data will be required, and what is the scope of the clinical program to obtain such data?
- To which branch/division within the FDA would this product be submitted for approval?

4.2.3.9. Payment and Reimbursement Path

How will the product/solution be paid for by the healthcare system?

- What comparable products or services are currently being covered?
- What are the relevant CPT/DRG/APC payment codes?
- What are the reimbursement rates for the relevant codes? What has been the trend in these reimbursement rates over time and expected in the future?
- If no reimbursement code(s) exist, what would be the necessary next steps to obtain reimbursement?

4.2.3.10. Project Plan and Product Development Milestones

This section shall include the project definition and project schedule. Please include the details of the project plan to be undertaken and specific milestones to be achieved within the scope of the requested project funding.

The project plan and schedule should encompass a period of work of approximately one year duration.

The schedule should graphically display (i.e. Gantt chart) the specific tasks and the timing of deliverables and other key milestones. It is recommended that the graphical schedule reflect a monthly schedule and not be based on fixed dates.

Reviewers will be considering the following questions:

- What is the ultimate endpoint of the product development plan?
- Have Go/No-Go decision milestones been established?
- Are the project milestones relevant to establishing commercial viability of the product?
- What is the critical path?
- What are the near-term value-inflection points? How have they been validated? By which stakeholders?

4.2.3.11. Personnel

List and describe the personnel that will comprise the project team. Provide abbreviated biosketches for the Principal Investigator and up to two other key team members in the Appendix.

Reviewer consideration will include:

- Is this the correct team for the present stage of the technology?
- What business/commercialization expertise exists on the team?

4.2.3.12. Budget and Funding Requirements

The federal direct cost budget limit for the project is $75,000 to be matched 1:1 with non-federal funds for a total project budget of up to $150,000. See Section 2.4 for more on the matching funds requirement.

Budget Narrative. Provide an explanation of the overall budget by category and milestones. Specify the source(s) and availability of the requisite cost share. Budget forms will be included in the Appendix. See Section 4.2.4.1.

Reviewers will be considering the following questions:

- Is the budget realistic and appropriate for achieving the stated project milestones?
- Is the budget tied to Go/No-go decisions?
- What is the source of matching funds, and is it available to be charged to the project?
- How much more funding is required to get to the next inflection point?

4.2.3.13. Potential Risks/Mitigation

Briefly describe any potential risks that exist in any of the foregoing sections 4.2.3.1 through 4.2.3.12 and how they can be mitigated.

4.2.4. Application Appendices

4.2.4.1. Budget Forms

Provide budget forms to detail the budget plan for the proposed project. Templates are available on the NCAI-CC website. In the forms include total project direct costs only (regardless of federal or matching source) and only for costs directly applicable to achieving the project plan objectives. Please provide one form for the total project and one for each of the major development milestones detailed in the plan.

4.2.4.2. Biosketches (Limit 3)

Insert abridged NIH biosketches for the Principal Investigator and up to two co-investigators/ collaborators. Include prior experience in product development and commercialization activities. Limit 4 pages per biosketch.

4.2.4.3. References (Limit 1 page)

Insert pertinent references, citations.

4.2.4.4. Supplemental Information Form

The supplemental information includes detail regarding prior or current project co-funding applications and cost share; animal, human subjects, and human stem cells studies information; and subcontract resources.

5. Forms

Copies of the Application Cover Page Form, Budget Form, and Supplemental Information Form follow for reference. Forms that may be filled out and incorporated into the application are available from the NCAI-CC website.

NIH National Heart, Lung, and Blood Institute

Ohio Third Frontier Innovation Creating Opportunity

TECHNOLOGY DEVELOPMENT PROGRAM
APPLICATION COVER PAGE

Applicant Name (First, Last, Degree)					
Applicant Email and Phone					
Institution/ Department					
Project Title					
Disease Space	**Cardiovascular, Lung, Blood, Sleep Disorder, Other**				
Technology Category (Select One)	**Diagnostic Assay, Biomarker, Diagnostic System, Device, Small Molecule Drug, Biologic Drug/Therapy, Therapeutic, Combination Product, Monitoring product/System, Healthcare Information/mHealth Product, Tool, Other**				
Project Description					
Total Project Budget	**$**	**NCAI Funds Request (not to exceed 50% of total budget)**	**$**	**Cost Match**	**$**
Resubmission? (Yes/No)					
Commercialization Office Contact Name and Email					
Contract Office Contact Name and Email					

Program Director/Principal Investigator (Last, First, Middle):

DETAILED BUDGET FOR INITIAL BUDGET PERIOD DIRECT COSTS ONLY	FROM	THROUGH

List PERSONNEL *(Applicant organization only)*
Use Cal, Acad, or Summer to Enter Months Devoted to Project
Enter Dollar Amounts Requested *(omit cents)* for Salary Requested and Fringe Benefits

NAME	ROLE ON PROJECT	Cal. Mnths	Acad. Mnths	Summer Mnths	INST.BASE SALARY	SALARY REQUESTED	FRINGE BENEFITS	TOTAL
	PD/PI							
SUBTOTALS →								

CONSULTANT COSTS	
EQUIPMENT *(Itemize)*	
SUPPLIES *(Itemize by category)*	
TRAVEL	
INPATIENT CARE COSTS	
OUTPATIENT CARE COSTS	
ALTERATIONS AND RENOVATIONS *(Itemize by category)*	
OTHER EXPENSES *(Itemize by category)*	

CONSORTIUM/CONTRACTUAL COSTS	DIRECT COSTS	
SUBTOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD *(Item 7a, Face Page)*		$
CONSORTIUM/CONTRACTUAL COSTS	FACILITIES AND ADMINISTRATIVE COSTS	
TOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD		$

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APPLICATION SUPPLEMENTAL INFORMATION (PAGE 1 OF 2)

Project Title				
Principal Investigator	Name			
	Title			
	Institution Affiliation			
If the project will have Co-Investigator(s), please provide information:	Name			
	Title			
	Institution Affiliation			
	Department Affiliation			
	Email			
	Phone			
If there are additional Co-Investigator(s), please attach additional Co-Investigator(s) information.				
Human Subjects	Does this project involve human subjects?	Yes ☐	No ☐	
	Is IRB approval pending?	Yes ☐	No ☐	N/A ☐
	Anticipated Approval Date			
Human Stem Cells	Does this project involve use of human stem cells?	Yes ☐	No ☐	
	Are stem cells embryonic (ESC) in origin?	Yes ☐	No ☐	N/A ☐
	Is IRB/CHR approval pending?	Yes ☐	No ☐	N/A ☐
	Anticipated Approval Date			
Animal Studies	Does this project involve animal studies?	Yes ☐	No ☐	
	Is IACUC approval pending?	Yes ☐	No ☐	N/A ☐
	Anticipated Approval Date			
	Please describe the animal model:			

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APPLICATION SUPPLEMENTAL INFORMATION (PAGE 2 OF 2)

Project Implementation Feasibility Questionnaire	
Is the project currently being funded by or subject to pending applications to any other federal agencies/programs?	Yes ☐ No ☐ In Progress ☐
If Yes or In Progress, please describe the source and amount of funds, and the funding period for the other funds.	
If you should receive an award, are all necessary personnel available to begin project work upon receipt of award or when needed in the project timeline?	Yes ☐ No ☐ In Progress ☐
If No or In Progress, please describe plan and timeline for personnel availability. This includes resolving any %FTE commitments or cost center sharing issues.	
Have requisite matching funds been identified, committed, and will they be available to be expended in parallel with the federal funding?	Yes ☐ No ☐ In Progress ☐
If Yes, please designate the amount of funds and the source. If No or In Progress, please describe the plan, source, and timeline for availability.	

Project Subcontractors	
Do you plan to subcontract elements of the project work?	Yes ☐ No ☐ To be determined ☐
If yes, or To be Determined, please identify the selected or potential subcontracting organization(s), location, work to be provided, and budget amount allocated to the subcontract.	