NCAI-CC NIH Center for Accelerated Innovations at Cleveland Clinic

TECHNOLOGY DEVELOPMENT PROGRAM

REQUEST FOR APPLICATIONS ■ JANUARY 2019 (ROUND 12)

KEY DATES

- RFA released – **January 7, 2019.**
- Letters of Intent due – **February 14, 2019.** Midnight Eastern Time.
- Selected LOI submissions invited to submit full applications – **March 14, 2019.**
- Project applications due – **April 25, 2019**. Midnight Eastern Time.
- Award notices – **July 2019.**
- Project kick-off meeting in Cleveland – **August 8, 2019** (Tentative)

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

For information Contact:

Email: NCAICC@ccf.org
Telephone: 216-444-5322

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TECHNOLOGY DEVELOPMENT PROGRAM

REQUEST FOR APPLICATIONS - JANUARY 2019

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, the estimated economic cost for cardiovascular, lung, and blood diseases exceeds $400 billion, nearly one-quarter of the total economic costs of illness, injuries, and death in the United States. In addition, cardiovascular and lung diseases account 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 $10.2 million in grant funding from NHLBI plus subsequent supplements, and was 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 with technologies that span the range of diagnostics, diagnostic systems, devices, therapeutics and tools.

2. To select, fund, and guide projects through a process of rigorous external 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 (ESC) 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 of projects submitted for funding consideration.

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.

An investigator may only submit one Letter of Intent in a funding cycle.

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 one year.

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 in vivo efficacy 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
- Commercialization strategy

C. Project Plan

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

More detailed application review criteria are provided in Section 4.

2.4. Funding Awards

A total of up to $150,000 in direct project 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 (Cost Share) Requirement. One half of the total direct project budget must be supplied by non-federal funds. The matching funds are intended to be provided through an institution-managed funding source. The matching funds source must be identified at time of application and funds must be available to be applied in parallel with the federal funds during the project period.

Indirect Costs. In addition to the federal funds for the direct project costs, NCAI will provide Facilities and Administrative (F&A) funds in an amount equal to the federal share of the project funding multiplied by the applicant's institution federally approved F&A 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 continued 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. Request for Applications (RFA).
2. Letter of Intent (LOI) submission.
3. LOI review, applicant selection, invitation to submit full proposal.
4. Full application submission and review.
5. Funding decision and grant administration.
6. Project kick-off meeting.
7. Project execution and management.
8. Follow-on progress reports.

3.1. Request for Applications

Requests for Applications (RFA) under the Technology Development Program are issued 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. Letter of Intent

The Letter of Intent (LOI) shall include the following contents, submitted in one single combined unlocked PDF file. The letter of intent cover page includes a link for LOI submission.

Letter of Intent Cover Page. Download from the NCAI website Technology Development Program page.

Project Description. Narrative including the following sections and content. Limit 2 pages in total.

A. Project Definition. Provide a clear and succinct definition of the proposed product/solution incorporating one selection each from the lists of product categories, purposes, and clinical application categories below.

- Product category
  - diagnostic assay
  - biomarker
  - diagnostic system
  - device
  - small molecule/peptide drug
  - biologics therapy
  - combination product
  - monitoring product/system
  - healthcare information/mHealth product

- Purpose
  - prevention
  - diagnosis
  - treatment
  - monitoring
  - management

- Clinical application category
  - cardiovascular
  - pulmonary
  - blood (non-cancer)
  - sleep disorder

B. Unmet Need and Market Opportunity. Describe the significant unmet need and market opportunity addressed. Describe the specific patient population or market segment including the target market size in terms of numbers of patients and/or procedures, both in the U.S. and worldwide. Describe how the product/solution will provide measurable, meaningful advantages and benefits in the area of speed, size, cost-saving, ease of use, safety, efficacy, accuracy, productivity, outcomes or combination of these areas.

Letter of Intent, cont.

C. Project Background. Describe the scientific rationale for the project and approach. Summarize research and development conducted to-date leading to readiness for commercially-directed project activities.

D. Project Plan, Milestones, and Commercialization Strategy. Describe the project plan and goals, including specific milestones to be achieved during the project period. Describe how successful completion of the project will materially advance the technology development towards commercialization. Describe the ultimate development and commercialization strategy for the technology after completion of the project.

References and Biosketches. In addition, include a list of references or citations (not to exceed one page), plus abridged NIH biosketches for the Principal Investigator and up to two (2) co-investigators/ collaborators. Include prior experience in product development and commercialization activities. Limit 4 pages per biosketch.

3.3. Initial Review

NCAI-CC personnel, partner institution representatives, and members of the External Selection Committee (ESC) will review the submitted LOIs to evaluate fit for the NCAI-CC program, and for commercial opportunity.

Selected projects will then be invited to submit a full application for the next phase of evaluation. Only invited applications will be considered for further evaluation.

3.4. 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 will be 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.

Accepted applications will be reviewed by the 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, the U.S. Patent and Trademark Office, the Centers for Medicare and Medicaid Services, and healthcare system personnel.

3.5. Funding Decision and Award Implementation

Funding decisions will be communicated via email followed by official notice of grant award. Funding will be provided 50% from NCAI (federal) funds and 50% cost share from non-federal institution funding source(s). Award management will be conducted under terms of a subgrant agreement or letter of commitment. In either case, the agreement will specify the terms of funds distribution, requirements for providing cost share, and methods for funds disbursement.

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

3.6 Project Kick-Off Meeting

During commencement of the project period, NCAI will conduct a project kick-off meeting in Cleveland. Attendance will be mandatory for the PI for each funded project. Up to two other members of the project team are also invited to attend. The purpose will be to review and update the project plan as necessary, to review grant administration procedures, and to receive certain commercialization strategies education. See Section 4.2.3.12 for budget considerations.

3.7. 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.

3.8. Follow on Progress Reports

After completion of the NCAI-funded project activities, awardees will be requested to provide 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

- LOIs and 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, including preliminary data
    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
    14. Commercialization Strategy
- 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. It should incorporate a clear and concise product definition, a description of the commercial rationale and opportunity, a list of the project goals/milestones to be achieved, and a statement of the strategy for continued development beyond the project period.

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 preliminary data has been generated to indicate reasonable potential for the product/solution to delivery clinical efficacy or benefit?
- 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/peptide drug
  - biologics therapy
  - 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 improvement in the area of speed, size, cost-saving, ease of use, safety, efficacy, accuracy, productivity, outcomes 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?
- Is the project dependent on any intellectual property that is not controlled by the applicant or applicant's institution that could potentially impact commercialization?
- 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

Provide a preliminary Target Product Profile that describes the key quantifiable advantages and benefits 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:

- Intended use or indication for use statement.
- Expected regulatory pathway.
- Safety or efficacy data that will be required; 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 one year in 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?
- How are the project milestones relevant to establishing commercial viability of the product?
- What is the critical path?

4.2.3.11. Personnel

List and describe the personnel that will comprise the project team and any consultants or subcontractors that will contribute. 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 to execute the project work at the present stage of the development?
- Have appropriate consultant or business resources been identified to provide necessary outside services?
- Is there relevant clinical, regulatory, business, and commercialization experience represented to guide the project?

4.2.3.12. Budget and Funding Requirements

Provide a budget narrative which describes the overall budget by expense category and milestones. Specify the source(s) and availability of the requisite non-federal matching funds.

The federal direct cost budget limit for the project and matching funds (cost share) requirement are described in Section 2.4.

The budget may include only direct costs specifically applicable to achieving the stated project objectives. Travel or conference attendance expenses are not allowable unless directly related to achieving specified project milestones. Publication expenses are not allowable. Project team member student tuition or other education expenses are not allowable. F&A costs are not to be included in the budget, but will be added to federal funds disbursement as appropriate in the process of grant administration.

In addition to the direct project cost budget, applicants from institutions not in Cleveland may request direct cost funds for travel, lodging for one night, and meals to attend the mandatory project kick-off event at Cleveland Clinic. The P.I. and up to two project team members should be included. Actual expenses incurred will be reimbursed 100% from NCAI funds – no matching funds are required.

A budget form template is included in the Appendix and is available for download from the NCAI website. See also Section 4.2.4.1.

Budget and Funding Requirements, cont.

Reviewers will be considering the following questions pertaining to budget:

- Is the budget realistic and appropriate for achieving the stated project milestones?
- Does the budget reflect appropriate levels of effort for all team members?
- 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?

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.

4.2.3.14. Commercialization Strategy

Describe the plan for continued development of the technology after the project period, including funding strategy, licensing or company formation strategy, and strategic partnering strategy, including any engaged or prospective partners.

Application Appendices

4.2.4.1. Budget Forms

Provide budget forms to detail the budget plan for the proposed project. An editable form template is available on the NCAI-CC website.

Provide one form for the total project and one for each of the product development milestones detailed in the project plan (Section 4.2.3.10). Include only direct costs specifically applicable to achieving the stated project objectives.

If you are requesting funds to attend the project kick-off meeting in Cleveland, please include that on a separate budget form.

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 two page supplemental information form 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 Letter of Intent Cover Page Form, 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

NCAI-CC NIH Center for Accelerated Innovations at Cleveland Clinic

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LETTER OF INTENT 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	**Diagnostic, Diagnostic System, Device, Therapeutic, Tool, Other**	
Project Description (Limit 150 words)		
Resubmission? (Yes/No)		
Commercialization Office Contact Name and Email		

Please submit your Letter of Intent through the website upload link below which will open one week prior to due date:
http://www.ncai-cc.ccf.org/app/upload/?000&LOI

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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 (Limit 150 words)					
Total Project Budget	**$**	**NCAI Funds Request**	**$**	**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 PROJECT BUDGET FORM DIRECT COSTS ONLY	FROM	THROUGH

BUDGET CATEGORY (Please use separate page for each category):

- ☐ TOTAL PROJECT
- ☐ MILESTONE # (Please list each milestone on separate page.)
- ☐ PROJECT KICK-OFF MEETING

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	
PURCHASED SERVICES (e.g., CRO Costs, Subcontracted Services) *(Itemize)*	
SUPPLIES *(Itemize by category)*	
EQUIPMENT *(Itemize)*	
TRAVEL	
OTHER EXPENSES *(Itemize by category)*	
TOTAL DIRECT COSTS FOR CATEGORY	**$**

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APPLICATION SUPPLEMENTAL INFORMATION FORM (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☐
	Has IRB approval been received?	Yes☐ No☐ N/A☐
	Approval date or expected 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☐
	Has IRB/CHR approval been received?	Yes☐ No☐ N/A☐
	Approval date or expected approval date.	
Animal Studies	Does this project involve animal studies?	Yes☐ No☐
	Has IACUC approval been received?	Yes☐ No☐ N/A☐
	Approval date or expected approval date.	
	Please describe the animal model:	

TECHNOLOGY DEVELOPMENT PROGRAM

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 append a letter of commitment from the source designating the amount of funds and the availability date(s). If No or In Progress, please identify the source, the expected date of approval, the amount of funds, and availability dates(s).	
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. Will subcontracts be in place by the time needed to conduct the work according to the project plan timeline?	