

PCTC Visiting Scholar Award Program Guidelines

PCTC Visiting Scholar Funding Opportunities

This Request for Proposals provides funding for PCTC Visiting Scholar Awards up to \$25,000 for collaboration and exchange of expertise among PCTC Research Hubs.

The PCTC Visiting Scholar Award aims to stimulate innovative collaborations among PCTC Research Hubs along the translational research continuum. Applicants will travel to PCTC Research Hub laboratories to learn new techniques, exchange scientific knowledge or perform collaborative experiments to advance translational progenitor cell-based therapies for the treatment or diagnosis of heart, lung, or blood diseases.

Eligibility

- Any faculty member, postdoctoral fellow or graduate student affiliated with a PCTC Research Hub is eligible to apply for a PCTC Visiting Scholar Award. New or junior investigators are encouraged to apply.
- Individual investigators may submit only one proposal in response to this Request for Proposals as a PI, but can serve as a non-PI collaborator on other proposals.
- Eligible submissions must include collaboration of at least 2 of the PCTC Research Hubs.
- A letter from the host Research Hub contact Principal Investigator in support of the Visiting Scholar Award is required.
- Eligible submissions must include specific milestones and a realistic timeline in the range of weeks or a few months to be completed within a 12-month funding period.
- Awards will not be given for existing projects funded by other sources.

Regulatory Requirements/Approvals

Animal Studies

All grants that involve animal studies must be approved by the host Research Hub Institutional Animal Care and Use Committee (IACUC) prior to initiating any animal research activities. All other required institutional approvals (e.g. Biosafety registrations, Radiation Safety registration, etc.) must be obtained prior to initiating any research activities for which the certification/registration/approval is required. While advance approval by these bodies is not a prerequisite for submission of an application, award funds will not be released until all approvals have been obtained.

Human Subject Research

All awards with projects involving human subjects research must obtain Institutional Review Board (IRB) approval as well as satisfy other institutional requirements (e.g. Biosafety registrations, CITI training and HIPAA certification of staff, Clinical Engineering clearance of devices, Radiation Safety registration, etc.) prior to the release of grant funds.

Conflicts of Interest

At the time of application, before funds are awarded, and throughout the project period, it is the responsibility of the awardee and all members of the study team to report any financial or fiduciary interests that might appear to present a conflict of interest. These interests must be reported to the PCTC Administrative Coordinating Center. The presence of a conflict of interest does not disqualify investigators from receiving this award but will require the review and management of this conflict. The failure of any member of the study team to disclose all outside interests could result in the termination of award and the disallowance of study costs.

Potential Project Topics

Projects may cover a wide range of topics, including but not limited to the representative topics below:

- Pre-Clinical Translation
 - Development of pre-clinical research tools
 - Development of novel treatment platforms or therapies
 - Drug screening assays
 - Methods for generation of novel vaccines or peptides
 - Animal models for drug selection
 - Preclinical toxicology markers/assays
 - Surrogate marker assays, including genomic, proteomic assays, and metabolic, imaging methods

- Clinical Translation
 - Development of clinically relevant tools
 - Development and verification of surrogate marker assays
 - Clinical trial design paradigms (e.g., computer simulation)
 - Development or evaluation of diagnostic tests
 - Clinical trials including Pilot or Phase 1 trials
 - Collection of pharmacokinetics/pharmacodynamics data
 - Clinical physiology and mechanisms/pathophysiology of disease

- Post-Clinical Translation
 - Knowledge transfer
 - Novel approaches to enhance research
 - Tests of innovative applications of treatment

Funding Restrictions

- Requests must be no more than \$25,000 in direct costs. Budget requests must be realistic and well-justified in the budget justification.
- Allowable expenses: Travel costs (to be reimbursed to the Visiting Scholar directly by the PCTC Administrative Coordinating Center); research supplies; purchase or equipment rental, but new equipment costs should be no more than 20% of the total budget; salary support for staff team members, laboratory technician, recruitment and compensation of study participant costs; and research training for community partners.
- Unallowable Expenses: Administrative support, alterations or renovations of laboratory space, purchase of laboratory or office furniture, purchase of periodicals or books, phone services and professional society membership dues are not allowed. Salary support of trainees or faculty is not allowed.
- PCTC Visiting Scholar Award funds may be used for travel essential to the conduct of research, but not to present results at established meetings or conferences.
- Funding periods will be for 12 months only. No cost extensions may be approved on a case-by-case basis with strong justification for use of remaining funds at the end of the award period.
- No sub-contracts should be included in the budget.
- All funded projects will be required to submit **written progress reports** within six months of award to the assigned PCTC Administrative Coordinating Center to ensure that projects are meeting their

milestones and progressing according to approved timelines. A final progress report will be due within 90 days of the end of the award. **Failure to submit progress reports in a timely manner can have significant implications for the project, and may result in termination of funding.**

Role of the PCTC Administrative Coordinating Center

The PCTC Administrative Coordinating Center (PCACC) will provide guidance and answer questions related to the application and review process, the scope of work that is suitable for funding, and post-award activities. They will assist research teams in identifying resources needed for successful completion of research projects. They will review applications to ensure compliance with submission guidelines and may contact investigators to provide additional information. Throughout the award, PCACC will serve as project manager, monitoring the progress of the projects, and may provide guidance, resources, and feedback to ensure the proposed translational milestones are met.

Application Process

Prepare each of the following sections and assemble into one PDF file to submit by email to mterrin@som.umaryland.edu; alefever@som.umaryland.edu, and litang@som.umaryland.edu. Form templates are available on the PCTC website

Cover Page (limited to one page; use form template):

- Title of PCTC Visiting Scholar Award Project
- Names, Academic Rank, and Appointments of contact PI and all co-investigators
- Signature of PI(s)
- Signature of the Research Hub Principal Investigator indicating support for submission.

Abstract (limited to one page)

The abstract is not included in the 5-page Research Plan. It must be no longer than 30 lines of text, and follow the required font and margin specifications of the Research Plan (See Research Plan Guidelines to follow). **The abstract should not contain proprietary confidential information.**

The abstract should include:

- A brief background of the project;
- Specific aims, objectives, or hypotheses;
- The significance of the proposed research;
- The unique features, new collaborations, and innovation of the project;
- The methodology (action steps) to be used;
- Expected results;
- Relevance to the translational nature of the PCTC;
- and, Potential for improving the health of patients within the next 3-5 years.

Research plan (5-page limit, content and format described below in “Research Plan Guidelines”). The research plan should include the following sections:

Brief Introduction: This section is intended to help orient the reviewers to better understand the scientific basis for the project, why the work is being proposed as well as the suitability of the research for PCTC Visiting Scholar Award funding. Any new collaborations or highly innovative aspects should be succinctly noted. Relevance to the translational nature of the PCTC should also be indicated.

Project Milestones and Timeline: A **summary** of specific milestones and a timeline of the project must be included in the research plan. This summary may be presented as a chart, a paragraph, or incorporated throughout the experimental design. Milestones should highlight specific goals to be

attained and, when appropriate, hypotheses to be tested. Milestones must include both the scientific objectives of the application and the procedural issues involved in executing them in a realistic and achievable way. If new techniques, new populations, or new collaborations are utilized to reach these milestones, they should be emphasized. All grants must be organized towards the completion of project- and/or time-dependent milestones.

NOTE: *In contrast to the milestone/timeline summary presented in the research plan, the **Project Milestone Timeline** document (see template) that is required as part of the application **MUST** include the milestones described in the research plan AND a breakdown of all activities necessary to complete the milestone and the time required for each activity.*

Background (including Preliminary Results, if available), and Significance: In addition to scientific background and significance, this section may indicate how success of the Visiting Scholar Award will affect subsequent research and how it enhances translation (e.g., from lab to clinic). The material on Significance should indicate relevance to the overall target of clinical translation. It should also clarify how the research will advance the field, and **should also discuss the project's potential for translating progenitor cell-based therapies within the next 3-5 years.**

Research Design: Method description should be sufficiently detailed to assure feasibility and validity. Details should focus on the novel aspects of the project rather than published or standard techniques. If obtaining data from human subjects, provide inclusion/exclusion criteria for study group(s), and briefly outline recruitment, consenting, and compensation plan if applicable. Statistical approaches to data analysis should be outlined where applicable. Quantifiable goals for the completion of each milestone should be delineated.

Statement of collaborative effort: Include a specific statement as to how the collaboration between investigators from each Research Hub is necessary to further the goals of the proposal. Include processes for maintaining communication and interactions between the Research Hubs and monitoring equitable distribution of credit.

Participation in PCTC Annual Meetings

- Each Visiting Scholar Award must include a plan for at least one abstract submission to an PCTC Annual Meeting.
- Each Visiting Scholar Award must result in at least one poster or presentation at an PCTC Annual Meeting.

Anticipated Problems and Possible Solutions: Any anticipated experimental or interpretive problems should be addressed, with alternative approaches described when possible. The feasibility of using alternative approaches to complete the project within the constraints of the presented budget as well as the 12-month time limit of this grant must be assured in the application. All risks and drawbacks from using any proposed alternative approach must be addressed, especially if human subjects are involved.

Plan for Continuing Collaboration

Identify future collaboration that will result from the Visiting Scholar Award. Identify NIH, NSF, DOD, or other external funding opportunities that the collaborators will be prepared to apply for within 24 months of the start of the award.

Comprehensive budget

- Applicants **should** use the budget template available at the PCTC website but may customize it as their project requires.
- The budget **should** be **itemized** to within \$1,000.
- List each component of equipment with amount requested separately and justify each purchase.

- **Itemize supplies in separate categories**, such as glassware, drugs, chemicals, radioisotopes, etc. Categories in amounts less than \$1,000 do not have to be itemized.
- If animals are to be purchased, state the species, number to be used, and cost per animal.

Detailed budget justification

- A **detailed** budget justification is required and **should** include salary, supplies, equipment, travel, and any other expenses required to complete the study.
- The budget justification **MUST** include an explanation of other funding sources that will be used to cover costs not covered by PCTC Visiting Scholar Award funds.

Biographical sketch information

- A biographical sketch in NIH-format for the PI(s) (5-page limit)
- A biographical sketch in NIH-format for each Co-Investigator and other study team personnel (5-page limit)
- Full “Other support” pages from PI and all named Co-Investigators

Project Milestone Timeline

- Applicants **MUST** use template provided on PCTC website

Project application checklist

- Applicants **MUST** use template provided on PCTC website
- Incomplete checklists will be returned to the study team for completion

Reference list of up to 30 references

Regulatory Approvals (IRB and IACUC).

Research Plan Guidelines

Presentation and Formatting: The research plan must be no longer than five single-spaced pages (including figures) in a font no smaller than 11 points, with margins of at least 0.5 inches on all sides. **The abstract and references are not included in the five-page limit.** The name of the contact PI should appear in the top right-hand corner of each page. Page numbers should appear on the bottom right-hand corner of each page.

PCTC Visiting Scholar Award Criteria and Process

Applications will be evaluated and scored using the following six criteria:

1. **Relevance to translation:** Are there plans to move the project through to the next step along the research pathway?
2. **Scientific impact, novelty, and merit, including experimental design**
3. **Feasibility of project completion within a 12-month period**
4. The **creation or potential for creation of collaborations** between investigators and/or academic-community partnerships
5. Whether or not the project’s PI is a **junior investigator** and/or will promote the development of new translational researchers by **moving junior or senior investigators into a new research area**
6. The **extent of collaboration** between PCTC Research Hubs that will result from this Visiting Scholar Award.

PCTC Visiting Scholar Award Program Cover Page

PROJECT TITLE:	
PRINCIPAL INVESTIGATORS (Affiliations):	

Lead Principal Investigator (PI):

1. Lead PI Contact Email:
2. Lead PI Phone number:
3. Research Hubs involved in this PCTC Visiting Scholar Award:
 - a. -
 - b. -
 - c. -

PCTC Visiting Scholar Abstract

PROJECT TITLE:	
PRINCIPAL INVESTIGATORS (Affiliations):	

Please include, in no more than 30 lines: A brief background of the project; Specific aims, objectives, or hypotheses; The significance of the proposed research; The unique features, new collaborations, and innovation of the project; The methodology (action steps) to be used; Expected results; Relevance to the translational nature of the PCTC Visiting Scholar Award and; potential for improving the health of patients within the next 3-5 years.

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PCTC Visiting Scholar Award Program Projected Collaboration Timeline

PROJECT TITLE:	
PRINCIPAL INVESTIGATORS (Affiliations):	

Please include your project milestone(s) and the related research activities, checking the box according to the anticipated time to complete each. You may add or remove activity rows or milestones as required. Please include this in your application package.

MILESTONE #1: {Insert milestone here and list steps below.}		Months 1-3	Months 4-6	Months 7-9	Months 10-12
1A		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1B		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1C		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MILESTONE #2: {Insert milestone here and list steps below.}		Months 1-3	Months 4-6	Months 7-9	Months 10-12
2A		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2B		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2C		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

MILESTONE #3: {Insert milestone here and list steps below.}		Months 1-3	Months 4-6	Months 7-9	Months 10-12
3A					
3B					
3C					

PCTC Visiting Scholar Award Program Budget Template

You may modify the budget template to suit your project's needs. Use major categories headings such as those provided as examples, listing individual items for each. The budget must be itemized to within \$1000, so items costing less than \$1000 need not be further broken down.

PROJECT TITLE:	
PRINCIPAL INVESTIGATORS (Affiliations):	
PROJECTED START DATE:	

*PERSONNEL			
Name	Role on Project	Proposed Salary to be Covered by Pilot Award	
			PERSONNEL TOTAL COST:
			\$
EQUIPMENT AND SUPPLIES			
Type of Equipment/Supply	Cost per Unit	# of Units	
			EQUIPMENT TOTAL COST:
			\$
TRAVEL			
Purpose of Travel	Name of Personnel Traveling	Registration/Lodging/Food Cost	
			TRAVEL TOTAL COST:
			\$

*Staff only. Investigator salaries are not allowed.

ANIMALS		
Type of Animal	Cost per Animal	# of Animals
		ANIMALS TOTAL COST:
		\$
PARTICIPANT SUPPORT		
Type of Support	Cost per Unit	# of Units
		PARTICIPANT SUPPORT TOTAL COST:
		\$
MISCELLANEOUS (including contracted work)		
Type of Expense	Cost per Unit	# of Units
		MISCELLANEOUS TOTAL COST:
		\$
TOTAL PROJECT COSTS:		\$

BUDGET JUSTIFICATION

Personnel:

Equipment and Supplies:

Travel:

Animals:

Participant Support:

Miscellaneous:

PCTC Visiting Scholar Award Program Application Checklist

- Cover page with administrative information
- Cover letter (if requesting faculty salary support, letter should state so and include the department chair signature(s))
- Abstract (30-line count max.)
- Specific aims page (limit to 1 page)
- Project plan description (no more than 5 pages)
- Milestones timeline
- Budget table and budget justification
- References (no more than 30)
- Biosketch(es) for PIs and co-investigators in 5 page NIH format
- Approvals, if applicable (IRB, IACUC). If approvals are pending at time of application, then list as pending. Award funds will not be released until appropriate approvals are obtained.