



2010 Colorado Clinical and Translational Sciences Institute (CCTSI) Novel Clinical and Translational Methods Application Process

ONLY CCTSI MEMBERS are eligible for these awards. To become a member, please go to the CCTSI website (CCTSI.UCDenver.edu)

I. Purpose

- The Novel Methods Grant Program of the CCTSI is a series of one-year awards meant to encourage cross-disciplinary and collaborative development of Novel Methods in Clinical and Translational Research. Awards are up to \$25,000.

The purpose of these awards is the creation of new collaborations for Novel Method Development. The goal is to help a researcher who has a strong research question but no established method to address the question and who lacks the expertise to develop the method themselves. The Novel Methods Grant program is designed to help such investigators find new collaborators with the relevant expertise and to provide funds to support that new collaboration's development of novel methodology. The identification of investigators with strong research questions but who lack an appropriate method is termed Phase I of the program. The best Phase I scientific ideas will then be released to the CCTSI community to help identify a new collaborator with the necessary skill. **Please see the Frequently Asked Questions pages for additional details.**

Alternative CCTSI programs including pilot awards specific to Maternal and Child Health, pilot awards focused on Community based research, and a general pilot award program (the CO-Pilot program) are administered through separate RFAs. If your research focuses on pilot work with an established method, if you are part of an established collaborative relationship, or if you have the expertise to solve your own methodological need, please consider these alternative options for pilot funding.

For the Novel Methods Development Program, **translational** research is intentionally broadly construed and includes any basic (animal or laboratory), pre-clinical, clinical (Step 1 translational), behavioral, and Step 2 translational research with promise to improve health.

II. Key Dates

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|--|-------------------|
| Posted Date: | 28 September 2009 |
| Phase I Letter of Intent Due | 26 October 2009 |
| Phase I Submission Date | 23 November 2009 |
| Posting Date for Phase II Requests for Proposals | 25 January 2010 |
| Phase II Letter of Intent Due | 22 February 2010 |
| Phase II Submission Date: | 22 March 2010 |
| Earliest Anticipated Start Date: | 03 May 2010 |

III. Descriptions



The purpose of Novel Method Development awards is to support new collaborations oriented towards Novel Method Development for clinical and translational research. To foster new collaborations, the application process contains 2 phases.

Phase I: Identify Novel Methodological Development Need

Investigators with promising clinical or translational research interests but whose progress is limited by a specific methodological issue may submit an application describing the novel methodological need.

Phase II. Novel Method Development Plan.

The most promising Methodological needs identified from Phase I applicants will be released as RFAs. Phase II applications will be accepted from any member of the CCTSI community.

IV. Eligibility

- YOU MUST be a CCTSI Member to apply for an Award.
- Proposed methods development must represent a cross-disciplinary effort.
- One proposal per faculty member, and each faculty member may participate in only one application
 - Underrepresented and minority researchers (including women) who meet the program requirements are particularly urged to apply.

V. Application Requirements

Phase I

Phase I: Letter of Intent: Submit, by 26 October, 2009, the attached Cover page with project title and investigator names as your Letter of Intent. Submit your information to Sarah Stallings by email (sarah.stallings@ucdenver.edu). **Any investigator listed as a co-investigator on a Phase I application will not be eligible to submit a companion Phase II application.**

Awardees will provide a summary of the award's impact at the end of the granting period, including a list of any publications, patents, follow-on support or other outcomes, and must recognize the funding from the CCTSI on all publications relevant to the award.

Phase I Application Process: Components of the application are listed below. Maximum length for parts 2 and 3 is two pages.

| Phase I: Novel Methods Development Application | |
|--|---|
| 1. | Cover page |
| 2. | Goals, objectives or aims. (suggested 1/2 page) Provide a clear, concise summary of the novel methodology to be developed. What clinical or translational research areas will this novel methodology apply to, what questions will it answer? Identify the requesting investigator(s). |
| 3. | Rationale or background. (suggested 1 page) |



Briefly cite the background which led to the current request? Describe current methodology available and how the proposed methods development is different from already available techniques. Briefly explain why the novel methodology may be important.

Phase I Submission : All application materials should be submitted together by email to Novel Methodology Grants, care of (sarah.stallings@ucdenver.edu).

Phase II

Phase II: Letter of Intent: Submit, by April 3, 2009, the attached Cover page with project title and investigator names as your Letter of Intent. Submit your information to Sarah Stallings by email (sarah.stallings@ucdenver.edu). **Any investigator listed as a co-investigator on a Phase I application will not be eligible to submit a companion Phase II application.**

Awardees will provide a summary of the award’s impact at the end of the granting period, including a list of any publications, patents, follow-on support or other outcomes, and must recognize the funding from the CCTSI on all publications relevant to the award.

Phase II Application Process: Components of the application are listed below. Maximum length for parts 2 -7 combined is four pages.

Phase II: Parts of a Methods Development Plan

The Methods Development Plan does not need to discuss the rationale for needing novel methods development as that was covered in the Novel Methods Development Analysis. Instead focus on the process for developing the novel method(s).

| | |
|----|--|
| 1. | Cover page |
| 2. | Goals, objectives or aims of your project. (suggested 1/2 page; this may extensively utilize the RFA) Provide a clear, concise summary of the novel methodology to be developed. What clinical or translational research areas will this novel methodology apply to, what questions will it answer? |
| 3. | Novel methodology to be developed. (suggested 1-2 pages) Clearly describe the overall plan for methods development. Describe proposed tests, procedures, subject population and ages in sufficient detail to allow adequate evaluation of your approach. Include a projected time-line. |
| 4. | Requesting Investigator (suggested ½ page) |



| | |
|----|--|
| | Describe how the requesting investigator was included in the creation of this plan and how the requesting investigator will continue to be involved. |
| 5. | Educational mission. (suggested ¼ - ½ page) Describe how this proposal relates to the educational mission of the institution. Are there K12 awardees, residents, or students involved in the project? |
| 6. | Budget. (maximum \$25,00. No indirect costs are allowed. a. Justification: Justify items by categories. b. Other support (see below) Budgets should be specific with a maximum budget of \$25,000. No indirect costs are allowed. Please provide information as to other sources of funding that are involved in this project; how this proposal differs from those proposals, and any other sources of funding that may have been sought. |
| 7. | Include an NIH biosketch for each key personnel on the project. |

Phase II Submission : All application materials should be submitted together by email to Novel Methodology Grants, care of (sarah.stallings@ucdenver.edu).

IV Review Criteria

Peer review panels, convened by Dr. Randy Ross and Dr Kristi Anseth, will be responsible for award decisions. Reviewers with appropriate expertise will evaluate eligible applications with a specific emphasis on research that furthers the CCTSI mission. All decisions will be final, and no critiques will be supplied to applicants. Factors that will be considered in the success of the application are:

Phase I

- **Novelty** – How does the methodological need differ from already established methodologies
- **Potential Utility** - Will the proposed method have clinical or translational utility
- **Importance** – relative benefit compared to currently available methodologies

Phase II

- **Novelty** – How does the methodological need differ from already established methodologies
- **Potential Utility** - Will the proposed method have clinical or translational utility
- **Importance** – relative benefit compared to currently available methodologies
- **Methods Development Plan** – including feasibility
- **Involvement of Phase I requesting Investigator** – since the goal is to meet a need of a requesting investigator, the development plan should include involvement of the requesting investigator



- New multidisciplinary collaborations – the degree to which the Development plan represents a cross-disciplinary effort and the degree to which that collaboration is a new collaboration
- **The relevance of the Development Plan to CCTSI's educational mission** –the role of new investigators (including K-awardees) and students in the Development plan

Questions about the program should be addressed to Randy Ross (randy.ross@ucdenver), Novel Methods Director.

2009-2010 CCTSI

Novel Clinical and Translational Methods (NCTM)

Frequently Asked Questions

Do I have to be a CCTSI member to apply for the Novel Clinical and Translational Methods Program grant?

Yes. Please become a member at CCTSI.UCDenver.edu

What kinds of Phase I applications is the Novel Clinical and Translational Methods Program looking for?

The basic idea of the Novel Methods small grants is to support investigators who have a clinical or translational research question but who can't proceed because of the lack of an available method. Developing that method may be a relatively minor matter (i.e. may cost under \$25,000), but the initial investigator doesn't have the expertise to solve the problem themselves. Our goal is to bridge the gap to help them find the support they need to develop that novel method. One of our central tenets is that the breadth of novel method possibilities is tremendous, ranging from a new lab test, to a statistical technique, to a new software program, to ... A small group of individuals, no matter how well intentioned, can't identify all the novel methods needs so Phase I of our process is to ask investigators what novel methods they need.

A responsive Phase I application would be presented in terms of a research question which the requesting investigator can't pursue because of the lack of a method that the Phase I investigator him or herself don't have the expertise to solve.

What is the role of the Phase II applicant?

The NCTM committee will review and rank-order Phase I requests, and release a few as specific RFAs to the general CCTSI community looking for proposed solutions. It may be that someone the Phase I investigator has already talked to may be in a position to provide the optimal Phase II proposal, but it will be opened up to anyone who wants to compete for the chance to solve the methodological problem. Phase I applicants are expected to respond to questions for any individual seeking to submit a Phase II application.

Does the Phase I application need a budget?

The Phase I investigator doesn't get money, but, if supported by the NCTM program, should get the novel method they need; the Phase II proposal will contain the budget to help the Phase II investigator develop the method and then provide that solution to the Phase I investigator. Thus, the Phase I investigator doesn't submit a budget.



Can an investigator submit a Phase II application to solve their own Phase I request?

No. The NCTM is to support investigators who do not themselves have the expertise to solve their own methodological problem. Investigators needing financial support to solve their own methodological issues should consider requesting support through one of the other 3 CCTSI small grant programs; details about these programs are available on the CCTSI website.

What type of relationship between Phase I and Phase II applicants is considered an established relationship? The review process will favor proposals where there is not an already established relationship between the Phase I and Phase II investigators. An established relationship is defined as 2 individuals who share grant support or have a notable history of co-authored publications. Having talked with somebody about something sometime is not an established research relationship.



2009 Novel Methods Application

Name(s): _____

Department(s) and School/College: _____

Project Title: _____

Applying for:

- Phase I (identifying methodological need)
- Phase II (Novel Method Development Plan)

This application qualifies as:

- Underserved and Minority Investigator
- Female Principal Investigator