PHASE II NOVEL CLINICAL AND TRANSLATIONAL METHODS

Do you have the answer to a colleague’s methodological problem?

The Colorado Clinical and Translational Sciences Institute (CCTSI) is seeking proposals to provide $25,000 to develop a novel methodology specifically designed to help a colleague progress in their clinical or translational research.

We are seeking proposals focused on:

- Developing a novel drug screening method for pulmonary hypertension
- Create an imaging technique to correlate inflamed breast cancer and lymph node metastasis
- Develop a high resolution methods to identify critical lipid processing enzymes in the brain
- Develop a computer tablet-administered behavioral and physiological assessment of school and learning-related anxiety and self-regulation in early childhood
- Provide a novel method for pathogen-targeted transcriptional profiling method to characterize the physiological state of Mycobacterium abscessus, subspecies abscessus (M.ab) in clinical samples from patients undergoing treatment of lung disease
- Develop a method for targeted delivery of Calcineurin inhibition to leukemia cells

If you think you may be able to develop a methodology to solve this need, consider submitting a proposal to the CCTSI. Additional details on the methodological development need and on the application process can be found on the CCTSI website:

http://cctsi.ucdenver.edu/Funding/Pages/NCTM.aspx
2016 Colorado Clinical and Translational Sciences Institute (CCTSI) Novel Methods Phase II Application Process

I. Purpose
- The Novel Methods Grant Program of the CCTSI is a series of one-year awards meant to support requesting 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 feasible but outside of the expertise of the requesting investigator. Thus, the Novel Grant Program accepts requests for method development help and then forwards as a RFA the most meritorious of those requests to the CCTSI community. The high priority requests for 2016 are listed elsewhere in this announcement.
- 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 Methods Development. 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 request for applications (RFAs). If your research focuses on pilot work with an established method, please also consider these 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
- Posting Date for Phase II Requests for Proposals: 02 Feb 2016
- Phase II Letter of Intent Due (mandatory): 01 Mar 2016
- Phase II Submission Date: 22 Mar 2016
- Earliest Anticipated Start Date: 01 May 2016

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

Phase I: Identify Novel Methodological Development Need
In Phase I, Investigators submitted applications seeking a new collaboration to help with their methodological problems. Four of those applications have been identified as high priority methodological development needs and are now available for Phase II applications.

Phase II: Novel Methods Development Plan.
Phase II applications will now be accepted from any member of the CCTSI community. Phase II applications should (a) support a new collaboration between the Phase I and Phase II applicants and (b) should propose a solution for solving the methodological development need.

IV. **Eligibility**

- A primary goal of the Novel Methods Program is the development of new collaborations. Thus, any investigator listed on a Phase I application is ineligible to apply as part of a Phase II application responding to the Phase I request. Investigators who already have an established research relationship with the Phase I applicant team are also ineligible. An established collaboration is defined as sharing research support and/or a notable history of co-authorship.
- Investigators from non-affiliate institutions are ineligible to be Principal Investigators on Novel Methods Pilot Awards - but are encouraged to collaborate with an investigator from a CCTSI affiliate who would be eligible to serve as PI on an application. CCTSI affiliate institutions include: University of Colorado Denver, University of Colorado at Boulder, National Jewish Health, Denver Veterans Administration Medical Center, University of Colorado Hospital, Children’s Hospital Colorado, Denver Health, Kaisper Permanente of Colorado, and Colorado State University.
- Underrepresented and minority researchers are particularly urged to apply, as the CCTSI intends to contribute to the creation of a research workforce that is representative of the U.S. population. Groups that have historically been underrepresented in biomedical research include, but are not limited to, African Americans, Hispanic Americans, Native Americans (including Alaska Natives), natives of the U.S. Pacific Islands, individuals with disabilities and individuals from socially, culturally, economically or educationally disadvantaged backgrounds that have inhibited their ability to pursue research careers.
- Principal and Co-Investigators must be CCTSI members at the time of application. There are no exceptions and membership is free. Membership may be verified by clicking the button “Check your Member Status” at [http://cctsi.ucdenver.edu/Pages/Membership.aspx](http://cctsi.ucdenver.edu/Pages/Membership.aspx). Individuals may become CCTSI Members from the same webpage by clicking the appropriate membership type button and completing the online form.
- An individual may be a principal or co-investigator on more than one Phase II application.

V. **Application Requirements**

**Phase II:**

Interested investigators should consider the following steps:

A. Review the high priority methods development request below:

1. **Developing a novel drug screening method for pulmonary hypertension**

2. **Create an imaging technique to correlate inflamed breast cancer and lymph node metastasis**
3. Develop a high resolution methods to identify critical lipid processing enzymes in the brain

4. Develop a computer tablet-administered behavioral and physiological assessment of school and learning-related anxiety and self-regulation in early childhood

5. Provide a novel method for pathogen-targeted transcriptional profiling in human samples: A tool for monitoring treatment responses in tuberculosis

6. Develop a method for targeted delivery of Calcineurin inhibition to leukemia cells

1. Review the full requests online at the CCTSI website: http://cctsi.ucdenver.edu/Funding/Pages/NCTM.aspx

2. Work with the requesting investigator to clarify method development needs and goals.

3. Submit a methods development proposal as outlined below.

   **Phase II: Letter of Intent (required):** Submit, by the due date listed above, the attached Cover page with title, investigator names, and specifying which high priority request you are responding to. This Cover page is your Letter of Intent. Submit your information to Stephanie Vetter by email (stephanie.vetter@ucdenver.edu).

   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 2-5 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 Phase I Novel Methods Development Analysis. Instead focus on the process for developing the novel method(s).

All applications must have margins of 0.5”, utilize Arial font, and must have font size of 11 or greater. Sections 2-5 must, combined, be 4 or less pages in length. APPLICATIONS WHICH EXCEED THIS LENGTH WILL NOT BE CONSIDERED

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<td>Cover page, including identifying which high priority area is being applied for (a sample can be found at the end of this announcement).</td>
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<td>2.</td>
<td>Goals, objectives or aims of your project. (suggested 1/2 page; this may extensively utilize the request for applications) 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</td>
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questions will it answer? How it different than already available methodology.

3. Novel methodology to be developed. (suggested 1-2 pages)
   Clearly describe the overall plan for methods development. Describe proposed tests, procedures, subject population (if applicable) 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, fellows, residents, or students involved in the project?

6. Budget. (Maximum $25,000. 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.
   Budget requests are expected to vary widely dependent on the proposed method development project; however, the general conception of the program is that the budget is for methods development, not for pilot project data collection. Thus, most budgets will have the bulk to all of funds under the direction of the Phase II applicant. The benefit to the Phase I applicant is the acquisition of novel methodology. Phase I applicants, once the novel methodology is available, are not precluded from applying for pilot funding from other sources including CCTSI pilot project programs.

7. Include a NIH biosketch or similar abbreviated curriculum vitae (maximum 5 pages) 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 (stephanie.vetter@ucdenver.edu).

IV Review Criteria

Peer review panels, convened by Dr. Randy Ross 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 II
  • Novelty – How does the methodological need differ from already established methodologies?
• **Potential Utility** – Will the proposed method have clinical or translational utility within and beyond the proposed use?
• **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), trainees and students in the development plan

Questions about the program should be addressed to the Novel Methods Director Randy Ross (randy.ross@ucdenver.edu), or Program Administrator (stephanie.vetter@ucdenver.edu)
2016 Novel Methods Application

Name(s):

Department(s) and School/College:

Project Title:

Applying for:

- Phase II (Novel Method Development Plan)
  
  Priority Need (please choose one)

- Developing a novel drug screening method for pulmonary hypertension
- Create an imaging technique to correlate inflamed breast cancer and lymph node metastasis
- Develop a high resolution methods to identify critical lipid processing enzymes in the brain
- Develop a computer tablet-administered behavioral and physiological assessment of school and learning-related anxiety and self-regulation in early childhood
- Provide a novel method for pathogen-targeted transcriptional profiling in human samples: A tool for monitoring treatment responses in tuberculosis
- Develop a method for targeted delivery of Calcineurin inhibition to leukemia cells

This application qualifies as:

- Underserved and Minority Investigator
- Female Principal Investigator