



## REQUEST FOR APPLICATIONS PHASE II NOVEL CLINICAL AND TRANSLATIONAL METHODS

**Do you have the answer to a colleague's methodological problem?  
Could you use \$25,000 to develop it?**

The Colorado Clinical and Translational Sciences Institute (CCTSI) requests proposals for \$25,000 grants funding novel methods development specifically addressing clinical and translational research needs identified by your colleagues.

**Six specific methods needs have been identified (click on text to see full proposal in pdf):**

1. Software for stimulus presentation, recording, and analysis of smooth pursuit eye movements in infants and young children.
2. The development of a novel *in vitro* model based on stem cell technology to study varicella zoster virus latency
3. A highly sensitive method for rapid and large-scale quantification of phosphatidylglycerol and phosphatidylinositol in pulmonary surfactant derived from patients with acute and chronic lung diseases
4. To develop pharmacokinetics to identify whether deuterium enrichment and measurement is an improvement for measuring milk transfer during lactation in the very early postnatal period
5. Methodologies to screen for inhibitors of a transcription factor that is the product of the ERG gene, an extremely promising new target in prostate cancer
6. Methods to measure stress reactivity within a high risk and exceptionally mobile population of young adults who have a history of foster care placement due to maltreatment

**If you think you may be able to develop a methodology to solve one of these needs, consider submitting a proposal to the CCTSI.**

**Become a CCTSI member to be eligible ([Become a Member](#) or**

<http://cctsi.ucdenver.edu/Pages/Membership.aspx>)

**Additional details on the priority methods development needs and on the application process can be found on the CCTSI website ([2009-2010 Novel Methods RFA](#) or**

<http://cctsi.ucdenver.edu/Funding/Pages/NCTM.aspx>)



## 2009-2010 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 2010 are listed later 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. Up to 4 Phase II applications will be funded.

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	25 January 2010
Phase II Letter of Intent Due (required)	22 February 2010
Phase II Submission Date:	22 March 2010
Earliest Anticipated Start Date:	03 May 2010

### III. Descriptions

The purpose of the Phase II Novel Methods Development 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 (this has been completed)

In Phase I, Investigators submitted applications seeking a new collaboration to help with their methodological problems. **Six 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.
- Other than the limitation described above, any member of the CCTSI community is eligible to submit a Phase II application and may participate in the submission of Phase II applications for more than one request for applications. However, no individual may be listed on more than one Phase II application which is in response to the same high priority request. No individual may be listed on more than one final award.
- Underrepresented and minority researchers (including women) who meet the program requirements are particularly encouraged to apply.
- **YOU MUST BE A CCTSI MEMBER TO BE ELIGIBLE for the CCTSI NOVEL METHODS GRANT. Take a few minutes and BECOME A MEMBER today at this website: <http://cctsi.ucdenver.edu/Pages/Membership.aspx>**

#### V. Application Requirements

##### Phase II:

Interested investigators should consider the following steps:

A. Review the six high priority methods development requests below:

1. Requesting Investigator : Sharon Hunter ([sharon.hunter@ucdenver.edu](mailto:sharon.hunter@ucdenver.edu))

Topic: Software for stimulus presentation, recording, and analysis of smooth pursuit eye movements in infants and young children

2. Requesting Investigators : Katherine Lee ([katherine.s.lee@ucdenver.edu](mailto:katherine.s.lee@ucdenver.edu)), Myron Levin

Topic: The development of a novel in vitro model based on stem cell technology to study varicella zoster virus latency

3. Requesting Investigators : Kevin Brown ([brownk@njhealth.org](mailto:brownk@njhealth.org)), E Rand Sutherland

Topic: A highly sensitive method for rapid and large-scale quantification of phosphatidylglycerol and phosphatidylinositol in pulmonary surfactant derived from patients with acute and chronic lung diseases.

4. Requesting Investigators : Maya Bunik ([bunik.maya@tchden.org](mailto:bunik.maya@tchden.org)), Nancy Krebs, Jess Wahlig, Peggy Neville

Topic: To develop pharmacokinetics to identify whether deuterium enrichment and measurement is an improvement for measuring milk transfer during lactation in the very early postnatal period.

5. Requesting Investigator : Thomas Flaig ([thomas.flraig@ucdenver.edu](mailto:thomas.flraig@ucdenver.edu))

Topic: Methodologies to screen for inhibitors of a transcription factor that is the product of the ERG gene, an extremely promising new target in prostate cancer.

6. Requesting Investigators : Heather Taussig ([taussig.heather@tchden.org](mailto:taussig.heather@tchden.org)), Sara Culhane

Topic: Methods to measure stress reactivity within a high risk and exceptionally mobile population of young adults who have a history of foster care placement due to maltreatment.

- B. Review the full requests online at the CCTSI website:  
<http://cctsi.ucdenver.edu/Funding/Pages/NCTM.aspx>
- C. Work with the requesting investigator to clarify method development needs and goals.
- D. 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 Sarah Stallings by email ([sarah.stallings@ucdenver.edu](mailto:sarah.stallings@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	
<p>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 Ariel font, and must have font size of 11 or greater. Sections 2-5 must, combined, be 4 or less pages in length.</p>	
<b>1.</b>	Cover page, including identifying which high priority area is being applied for (a sample can be found at the end of this announcement).
<b>2.</b>	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 questions will it answer?
<b>3.</b>	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.
<b>4.</b>	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.
<b>5.</b>	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?
<b>6.</b>	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 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](mailto: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 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 Randy Ross ([randy.ross@ucdenver.edu](mailto:randy.ross@ucdenver.edu)), Novel Methods Director.

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# 2009-2010 Novel Methods Application

Name(s):

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Department(s) and School/College:

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Project Title:

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Applying for:

- Phase I (identifying methodological need)
- Phase II (Novel Method Development Plan)
  - Priority Need 1 – Software for infant eye tracking
  - Priority Need 2 – in vitro model to study varicella zoster virus latency
  - Priority Need 3 – quantification of phosphatidylglycerol and phosphatidylinositol
  - Priority Need 4 – pharmacokinetics of deuterium during lactation
  - Priority Need 5 – inhibitors of a transcription factor that is the product of the ERG gene
  - Priority Need 6 – stress reactivity in adults who have a history of foster care placement

This application qualifies as:

- Underserved and Minority Investigator
- Female Principal Investigator