2015-2016 CCTSI Novel Clinical and Translational Methods (NCTM) Pilot Program Request for Applications

The Colorado Clinical and Translational Sciences Institute (CCTSI) is pleased to announce this Request for Applications for the sixth year of the Novel Clinical and Translational Methods Pilot Program.

Applications submitted in response to this RFA must be associated with novel methods development for clinical or translational research. Note that this program has 2 phases: Phase I focuses on identifying novel method development needs; Phase II focuses on meeting those needs. Funding of up to $25,000 is available for Phase II projects.

This RFA is separate from other CCTSI Pilot opportunities in the Translational Pilot Program (CO-Pilot, CNS-Pilot, and CSU-CU Collaboration Pilot), Community Engagement Pilot Program (CE-Pilot), and the Child and Maternal Health Pilot Program (CMH-Pilot).

I. Purpose
The Novel Methods Pilot 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, and are contingent upon funding to the CCTSI from the National Center for Advancing Translational Science (NCATS), which is an institute of the National Institutes of Health (NIH).

The purpose of these awards is the creation of new collaborations for Novel Method development. The goal is to help a researcher who themselves 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 Pilot 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 identify in Phase II a new collaborator with the necessary skill. Please see the Frequently Asked Questions pages for additional details.

CCTSI pilot programs administered through separate RFAs including general translational research (Translational Pilot program including CO Pilots, CNS Pilots and CSU-CU Pilots), Community Engagement research (CE Pilot Program), and Maternal and Child Health research (CMH Pilot Program). 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 Pilot 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

<table>
<thead>
<tr>
<th>Event</th>
<th>Date</th>
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<tbody>
<tr>
<td>Posted Date</td>
<td>01 Oct 2015</td>
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<tr>
<td>Phase I Letter of Intent Due (mandatory)</td>
<td>24 Nov 2015</td>
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<tr>
<td>Phase I Submission Date</td>
<td>15 Dec 2015</td>
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<tr>
<td>Posting Date for Phase II Requests for Proposals</td>
<td>02 Feb 2016</td>
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<tr>
<td>Phase II Letter of Intent Due (mandatory)</td>
<td>01 Mar 2016</td>
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<tr>
<td>Phase II Submission Date</td>
<td>22 Mar 2016</td>
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<tr>
<td>Earliest Anticipated Start Date</td>
<td>01 May 2016</td>
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III. Descriptions

The purpose of Novel Method Pilot Program 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. Phase II applications may have proposed budgets up to $25,000.

IV. Eligibility

- Proposed methods development must represent a cross-disciplinary effort.
- One Phase I proposal per faculty member, and each faculty member may participate in only one Phase I application.
- 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 Boulder, National Jewish Health, Denver Veteran Administration Medical Center, University of Colorado Hospital, Children’s Hospital Colorado, Denver Health, Kaiser 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://www.ucdenver.edu/research/CCTSI/about/Pages/Become-a-Member.aspx. Individuals may become CCTSI Members from the same webpage by clicking the appropriate membership type button and completing the online form.
V. Application Requirements
Novel Methods Pilot Awards are federally funded form the CTSA grant, but do not require official pre-award review (routing) through the CU Denver Office of Grants and Contracts prior to submission. However, affiliate home organizations may require applicants to complete an internal review process prior to submission. Please check with your institutional grants or sponsored projects office to ascertain if your institution has pre-submission requirements for applications to programs such as this. Any awarded projects that have not met these requirements prior to submission will not be activated until all such affiliate institutional requirements are met.

If a Novel Methods Pilot Award is made to an investigator at an affiliated institution, F&A costs may be included. Please contact the CCTSI for specific discussions on how this may impact your overall budget prior to development and submission of your project.

All applicants are reminded to avoid public disclosure of results, in either text or verbal form, without first determining if intellectual property exists, as this may result in a lost opportunity to protect and commercialize your invention. Please call the TTO Office (303-724-0221) before presenting or publishing results.

Phase I
Phase I: Mandatory Letter of Intent: Submit by November 24, 2015, the attached Cover page with project title and investigator names as your Letter of Intent. Submit your information to Randy Ross by email (randy.ross@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.

<table>
<thead>
<tr>
<th>Phase I: Identify Novel Methodological Development Need</th>
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<tr>
<td>1. Cover page</td>
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<tr>
<td>2. Goals, objectives or aims. (suggested 1/2 page)</td>
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<tr>
<td>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).</td>
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<tr>
<td>3. Rationale or background. (suggested 1 page)</td>
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<tr>
<td>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.</td>
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Phase I Submission: All application materials should be submitted together by email to Randy Ross by email (randy.ross@ucdenver.edu). Phase I submissions are due by December 15, 2015.
Phase II

**Phase II: Mandatory Letter of Intent:** Submit, by March 1, 2016, the attached Cover page with project title and investigator names as your Letter of Intent. Submit your information to Randy Ross by email (randy.ross@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 2-6 combined is four pages.

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### Phase II: Novel Method Development Plan

The Novel 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 in Phase I. Instead focus on the process for developing the novel method(s).

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<tbody>
<tr>
<td>1.</td>
<td>Cover page</td>
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<tr>
<td>2.</td>
<td>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?</td>
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<tr>
<td>3.</td>
<td>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.</td>
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<td>4.</td>
<td>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.</td>
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<td>5.</td>
<td>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?</td>
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<tr>
<td>6.</td>
<td>Budget. (maximum $25,000. No indirect costs are allowed).&lt;br&gt;a. Justification: Justify items by categories.&lt;br&gt;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.</td>
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<td>7.</td>
<td>Include an NIH biosketch for each key personnel on the project.</td>
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**Phase II Submission:** All application materials should be submitted together by email to Randy Ross by email (randy.ross@ucdenver.edu) on or before March 22, 2016.
IV. Review Criteria
Peer review panels, chaired 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 I
- Novelty – How well have currently available methodologies been described. 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.
- Overall Quality

Phase II
- Novelty – How well have currently available methodologies been described. 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.
- Overall Quality

Questions about the program should be addressed to Randy Ross (randy.ross@ucdenver.edu), Novel Clinical and Translational Methods Pilot Program Director.
What kinds of Phase I applications is the Novel Clinical and Translational Methods Program looking for?
The basic idea of the Novel Methods Pilot Program 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 Novel Methods Pilot Program 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 Novel Methods Pilot 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 Novel Methods Pilot Program 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 CCTSI Pilot 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.
2015-2016 Novel Clinical and Translational Methods (NCTM) Pilot Program Application

Name(s): ______________________________________________________________

Department(s) and School/College: __________________________________________

Project Title: ___________________________________________________________

Applying for:

● Phase I (Identify Novel Methodological Development Need)
● Phase II (Novel Method Development Plan)

This application qualifies as:

● Underserved and Minority Investigator
● Female Principal Investigator