Clinical and Translational Pilot Grants Program
Request for Small Grants

Part 1. Overview Information

Funding Opportunity Purpose
The goal of this Request for Applications (RFA) is to support clinical and translational pilot investigations relevant to improving health in West Virginia and Appalachia.

Application Due Dates
Rolling Application

Applications must be submitted via email as a single PDF document, and should be sent to Wes Kimble at WKIMBLE1@hsc.wvu.edu.

Budget
For all funding cycles, the budget is limited to a maximum of $5,000 in total direct costs with a performance period of six (6) months.

New Compliance Processes
Researchers responding to this Pilot Grant RFA must include CITI certification for investigators conducting research amongst human subjects as well as documentation of IRB protocol submission. Documentation for these requirements should be included in the Appendix of the application.

Part 2. Full Text of Announcement

Section I. Funding Opportunity Description
The West Virginia Clinical and Translational Science Institute (WVCTSI) is accepting Pilot Project Funding applications for clinical and translational research focusing on, but not limited to, specific health areas of importance to West Virginia and Appalachia at large. Of note, projects with significant laboratory based components must have very clear delineation of the plan for translation of the research with impact on human health.

The National Institutes of Health (NIH) defines clinical research as: (1) patient-oriented research; (2) epidemiologic and behavioral studies; and/or (3) outcomes research and health services research. Per the NIH, translational research includes: the process of making discoveries in the research laboratory or in preclinical studies that will have an impact on human health and may lead to the development of studies in humans; the process of applying discoveries generated during research in the laboratory, and in preclinical studies, to the development of trials and studies in humans; and research aimed at enhancing the adoption of best practices in the community. Cost-effectiveness of prevention and treatment strategies are also important aspects of translational science.

Other Requirements for the Clinical and Translational Pilot Grants Program
The goal of the West Virginia Clinical and Translation Science Institute's (WVCTSI) IDeA CTR award is to expand the infrastructure for, and practice of, clinical and translational research to a level competitive for a Clinical and Translational Science Award (CTSA). To achieve this goal, all WVCTSI activities are focused upon three specific aims:

1. Grow the WVCTSI as an academic home and a catalyst for clinical and translational research that targets cancer, cardiovascular-stroke, and obesity related diseases;
2. Establish cross cutting research partnerships among the WVCTSI partnered institutions and collaborating CTSAs at University of Kentucky, Ohio State University, and Indiana University to increase our research capacity; and,
3. Utilize innovative recruitment, training, and mentoring strategies to develop clinical and translational scientists at each of the WVCTSI institutions.

The following priorities for pilot grants will be articulated to the review committee:

- Applications that have been favorably reviewed extramurally and/or by the WVCTSI that are re-submitted with clear responsiveness to previous critique and a plan for translational focus of the research.
- Proposals with investigator teams that include clinician scientists in key roles (PI/Co-PI) with clearly articulated plans for translational application of the research. Clinician investigators must contribute an appropriate amount of effort (minimum 10% effort for the PI) to the project and their roles must be clearly defined in the application.
- Proposals with strong potential to secure external funding; this potential will be evaluated based on the science as well as the PI (if single PI) or the team of investigators if Co-investigators are included in the application.
- WVCTSI thematic focus topics related to cancer, neuroscience, obesity and metabolic disease, cardiovascular disease, stroke and the risk factors associated with the aforementioned thematic focus topics.
- Applications in which Early Stage (ESI) and Junior Investigators propose pilot studies to obtain preliminary data for an extramural grant submission. An ESI is a new investigator who has completed his or her terminal research degree or medical or other professional residency—whichever date is later—within the past 10 years and has not yet been awarded a substantial, competing NIH research grant. For WVCTSI purposes, qualifying ESIs must have at least one year of eligibility remaining that meets the NIH definition of an Early Stage Investigator upon completion of their WVCTSI funded project. Junior Investigators and ESIs must identify a mentor to assist with the investigator's training with written documentation that the mentor is willing to serve in this capacity as well as a description of the mentoring team, if applicable.
- Applications intended to stimulate innovation and commercialization.

This RFA is an open competition for proposals that address the specific aims of the WVCTSI. To better address the specific aims of the WVCTSI, PIs are strongly encouraged to submit applications that address one of the following funding priority areas:

- Cancer
- Cardiovascular Disease
- Emerging Epidemics in Appalachia
- Neuroscience
- Obesity and Metabolic Diseases

Award Project Period
The scope of the proposed project should determine the project period. The maximum project period is six (6) months.

Section II. Eligibility Information

PI Eligibility is limited to the following:

- Faculty (all title series including regular, research, clinical, adjunct and special) of the WVCTSI member institutions (West Virginia University, CAMC-Institute/WVU-Charleston, and West Virginia School of Osteopathic Medicine (WVSOM)) who intend to apply for external funding in the future.
- Rural clinic physicians and community/practice-based researchers may serve as PIs, but must have a WVCTSI faculty member as a co-investigator on the research team/within the proposed Pilot application.
- The following personnel are not eligible to serve as PIs but may be co-investigators: investigators-in-training including residents, post-doctoral fellows, clinical fellows, and faculty member(s) with courtesy appointments.
- WVCTSI Leadership are restricted from submitting applications which will direct funds into her or his program or lab.
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Additional Information on Eligibility - Restrictions

- Leaders of Pilot projects must hold a faculty appointment or equivalent at the time the Pilot award commences. For the purposes of this RFA, these are individuals who can independently apply for Federal or non-Federal investigator-initiated peer-reviewed Research Project Grants (RPG). Individuals holding postdoctoral fellowships or other positions that lack independent status are not eligible to lead pilot projects.
- The Project lead for Pilot projects may not concurrently have research funding from other IDeA Program award mechanisms (e.g. INBRE, COBRE).
- Pilot projects may not overlap with other ongoing WVCTSI-funded projects.

Those with questions related to the various requirements may contact Dr. Anne Bolyard via email at aebolyard@hsc.wvu.edu with any questions or concerns.

Section III. Application and Submission Information

Format Specifications

Font restrictions: use a font size of 11 points or larger. The only acceptable fonts are the following: Arial, Helvetica, Palatino Linotype, or Georgia.

Font color: black only. Type density, including characters and spaces, must be no more than 15 characters per inch. Type may be no more than six lines per inch.

Page Margins: use standard paper size (8 ½" x 11). Use at least one-half inch margins (top, bottom, left, and right) for all pages. No information should appear in the margins. Specifically, do not enter the PI's name or page numbers in the margins (as was past practice with hard copy grant proposals). Do not include any information in a header or footer of the attachments.

Page Formatting: applicants are strongly encouraged to use only a standard, single-column format for the text.

Figures, Graphs, Diagrams, Charts, Tables, Figure Legends, and Footnote: you may use a smaller type size but it must be in a black font color, readily legible, and follow the font typeface requirement. Color can be used in figures; however, all text must be in a black font color, clear and legible.

Grantsmanship: use English and avoid jargon. If terms are not universally known, spell out the term the first time it is used and note the appropriate abbreviation in parentheses. The abbreviation may be used thereafter.

Page Limits: although many sections of your grant application are described as separate sections, the page limits must be followed or the proposal will be returned without review and not considered for funding. In addition, the appendix should not be used to circumvent the established page limits.

Application Instructions

Applicants are encouraged to review the instructions provided below carefully and to contact CTSI Pilot personnel with questions prior to the submission of your CTSI Pilot Grants Program application. The application must include the following (please utilize the application templates referenced):

Face Page: please complete NIH PHS 398 Face Page (Form Page 1) and NIH PHS 398 Form Page 3. NIH Forms

Project Abstract: please use NIH PHS 398 Form Page 2; abstract length is limited by the text box. The abstract should describe: 1) the scientific research plan, 2) how the proposed project promotes clinical and translational research, and 3) how the proposed research supports one of the funding priority areas. NIH Forms

Approach/Research Plan: please use NIH PHS 398 Continuation Page. This section is limited to 2 pages and should include Specific Aims, Background, Hypothesis, Significance Innovation, and Research Plan/Approach. Please use single space text. NIH Forms

- **Specific Aims/Objectives:** state concisely the goals of the proposed research and summarize the expected outcome(s), including the impact that the results of the proposed research will exert on the research field(s) involved. List succinctly the specific objectives of the research proposed, e.g., to test a stated hypothesis, create a novel design, solve a specific problem, challenge an existing paradigm or clinical practice, address a critical barrier to progress in the field, or develop new technology. Applicants must identify how the study objectives and outcomes are of benefit to West Virginia/Appalachian patients and communities.
- **Research Plan:** organize the Research Plan in the specified order and using the instructions provided below. Start each section with the appropriate section heading—Significance, Innovation, Approach. Cite published experimental details and provide the full reference in the Bibliography section. Given the length of the application, investigators should strive to provide a relevant, although not exhaustive bibliographic review (described below):

(a) Hypothesis

- Clearly and briefly define the hypothesis of the project

(b) Background

- Explain the importance of the problem or critical barrier to progress in the field that the proposed project addresses.

(c) Significance

- Explain how the project is of translational significance to the health of persons in West Virginia and/or Appalachia.
- Explain how the proposed project will improve scientific knowledge, technical capability, and/or clinical practice.
- Describe how relevant concepts, methods, technologies, treatments, services, or preventative interventions will be changed if the proposed aims are achieved.

(b) Innovation

- Explain how the application challenges and seeks to shift current research or clinical practice paradigms.

- Describe any novel, theoretical concepts, approaches or methodologies, instrumentation or intervention(s) to be developed or used, and any advantage over existing methodologies, instrumentation or intervention(s).
- Explain any refinements, improvements, or new applications of theoretical concepts, approaches or methodologies, instrumentation or interventions.

(c) Approach

- Describe in detail the overall strategy, methodology, sample selection and size, subject/patient enrollment, and analyses to be used to accomplish the specific aims of the project. Include how the data will be collected, analyzed, and interpreted as well as any resource sharing plans as appropriate.
- Discuss potential problems, alternative strategies, and benchmarks for success anticipated to achieve the aims.
- If the project is in the early stages of development, describe any strategy to establish feasibility, and address the management of any high risk aspects of the proposed work.
- Clearly describe how each partner will be engaged in the development and/or implementation of the pilot study.

As applicable, also include the following information as part of the Research Strategy, keeping within the three sections listed above: Significance, Innovation, and Approach.

- **Preliminary Studies**: please include information on any preliminary studies, if available. Discuss the PI's preliminary studies, data, and/or experience pertinent to this application. Preliminary data can be an essential part of a research grant application and help to establish the likelihood of success of the proposed project. This is not a requirement.
- **Translational Nature:** please include a paragraph at the end of application on the translational aspects of your application. Include a plan for translating and disseminating findings back to practitioners and/or community.

Human Subjects Protection Section: please use NIH PHS 398 Continuation Page (NIH Forms) and address all appropriate bulleted items below:

- 4.1.1 Risks to Human Subjects
- 4.1.2 Adequacy of Protection Against Risks
- 4.1.3 Potential Benefits of the Proposed Research to Human Subjects and Others
- 4.1.4 Importance of the Knowledge to be Gained
- 4.1.5 Data and Safety Monitoring Plan (For Clinical Trials only)
- 4.2 Inclusion of Women and Minorities
- 4.4 Inclusion of Children

Budget

For all funding cycles, the budget is limited to a maximum of $5,000 in total direct costs with a performance period of six months. Please use the NIH PHS 398 detailed budget form (Form Page 4); NIH Forms.

Allowable Costs

- Funds are to be used for the conduct of the project, including supplies, subject payments, assays, etc.
- Equipment essential for the conduct of the study
- Data analysis costs
- Project specific specimen collection/analysis or testing
- Chemistry and biological lab supplies
- Purchase of cell lines, cultures reagents etc.

- Animal purchase and housing costs.
- Specimen collection/analysis or testing
- Participant reimbursement

Unallowable Costs

- Funds cannot be used to support salary of the Principal Investigator or other investigators with faculty appointments. PIs must be listed as providing at least 10% effort concerning the project, however, this effort is not associated with salary, but only with time devoted to the project.
- Funding is not available for student stipends for thesis or dissertation projects.
- Funding will not be awarded as bridge funding for ongoing, competitive projects.
- Facilities and administrative costs, also known as indirect costs, are not permitted.
- Applicants must account for fringe benefit costs when considering research assistant salary levels.
- Salary and fringe support for administrative assistance, students, graduate students, clinical trainees, post-doctoral and clinical fellows are permitted
- Travel funds
- Publication fees
- Research assistant salary support
- Non-faculty personnel salary support

Budget Justification

Equipment: equipment costs (must be equal or greater than $5,000 single unit purchase price, useful life of one year or more) must be justified via a vendor quote for the item(s) you are requesting.
Materials and Supplies: Provide a list of the general types of expendable materials and supplies that will, in your estimation, be required to carry out the research you are proposing. Supplies should be broken down into common categories.
Consultants: Provide justification for the rate. If travel and subsistence costs are not factored into the consultant(s) cost, these should be justified separately, but still be considered a part of the total cost of the consultant(s).
Computer Costs: Provide vendor quote(s) or some other published source for the rate being charged to the grant. Also be prepared to justify why the computing needs could not be met using your office, department, or institutional computing resources.
Subcontracts/Subawards: Most of the justification for a subcontract should come from the sub award partner(s). Please refer to *Section VII. Clinical and Translational Pilot Grants Program Contact* to determine who you should contact if you have any additional questions regarding subcontracts/subawards.
Other Direct Costs: Provide quotes, catalog prices, or other published information to justify proposed rates for other costs.

New Compliance Process

For WVU Researchers: Certification of CITI training for protection of human subjects is required if the proposed projects includes research with humans and must be included in the Appendix of your application.

For Non-WVU WVCTSI Organizations: Certification of CITI training for protection of human subjects is required if the proposed projects includes research with humans and must be included in the Appendix of your application.

Appendix

- Project timeline and milestones (include time for IRB approval process and subject/patient enrollment in the timeline).
- Outline of clinical protocol (if study is an investigator initiated clinical trial and not described in the proposal).

- A Biosketch in NIH Format (4 page maximum for each investigator from a WVCTSI member organization) must be submitted for all key research personnel. NIH Forms Be sure to include the following sections in the biosketch; Section A - Personal Statement; Section B – Positions held and honors received; Section C – Selected peer-reviewed publications; and Section D – Research support.
- Other support in NIH format (one for each investigator from a WVCTSI member organization, no page limit). NIH Forms.
- Documentation on regulatory approvals (CITI training for Protection of Human Subjects, Animal Assurances, etc. if applicable),
- Letters of Support for PIs from the partnering universities/agencies/organizations, if applicable. Endorsement (ESI and junior investigators): To facilitate the effectiveness of the WVCTSI Pilot Grant Program in enhancing the research development of newly appointed faculty investigators, new investigators must provide a letter of endorsement and collaboration from a senior investigator who is willing to serve as a mentor for the applicant over the course of the project. This person must possess a M.D., Ph.D., Pharm.D., or other doctoral degree and must have sufficient clinical research expertise to serve as a mentor to the applicant. The letter should reflect the amount of time the mentor is willing/able to direct to this role as well as the specific types of activities that will be involved. These activities should include reviewing progress on the project, reviewing initial data, helping plan for future project funding after the pilot phase, discussing relevant research articles or related activities. It is NOT required that the mentor have funded effort.
- Mentoring and Career Development Plan (ESI and junior investigators): Please include mentor's information: Name, Degree(s), and Rank, Campus Address and Contact Information. Also include role and qualification of mentor(s). Inclusion of a clinician (physician, dentist, pharmacist, clinical psychologist, physical therapist, etc.) mentor is highly desirable in studies involving direct interaction with human participants. A career development plan must be in place to enhance clinical and translation research capabilities. This may include didactic coursework, the Clinical and Translational Science Seminar Series, and/or the Translational Science Spring/Fall Conference.
- Clinical and Translational Pilot Grants application from ESIs as well as junior investigators should be reviewed by her/his Mentoring Team prior to submission to the Clinical and Translational Pilot Grants program. The mentor should indicate this action was taken in the letter of support from the mentor.
- Letter from Supervisor/Department Chair: A letter signed by the immediate supervisor (e.g. Division Chief) and/or Department Chair that includes acknowledgement of their support for the project and providing assurance that sufficient protected time to complete the research will be available. No specific amount of protected time is required, but the review committee will consider the distribution of effort and other activities of the applicant. Please include the name, email, and telephone number of Department Chair.
- Bibliography/References: Authors, year, title and journal information is expected for each citation. Given the length of the application, investigators should strive to provide a relevant, although not exhaustive review (no more than 1 page).

Other Submission Requirements and Information

The Clinical and Translational Pilot Grants Program application package must be submitted as a single PDF document via email. If the Clinical and Translational Pilot Grants Program application package submitted by a PI does not meet all of the aforementioned requirements, the application will be returned to the PI without review and not considered for Clinical and Translational Pilot Grants Program funding.

Section IV. Application Review Information

Criteria

Only the review criteria described below will be considered in the review process.

Overall Impact

Reviewers will provide an yes/no decision to fund based on the assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following review criteria and additional review criteria (as applicable for the project proposed).

Scored Review Criteria
Reviewers will consider each of the review criteria below in the determination of scientific merit. An application does not need to be strong in all categories to be judged likely to have major scientific impact. For example, a project that by its nature is not innovative may be essential to advance a field.

Significance
Does the project address an important problem or a critical barrier to progress in the field? Does the project address an important problem or a critical barrier to addressing health disparities in West Virginia/Appalachia? If the aims of the project are achieved, how will scientific knowledge, technical capability, clinical practice and/or patient and community health be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

Investigator(s)
Are the PD(s)/PI(s), collaborators, and other PIs well-suited to the project? If Early Stage Investigators or New Investigators, or in the early stages of independent careers, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?

Innovation
Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

Approach
Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed?

If the project involves human subjects and/or NIH-defined clinical research, are the plans to address 1) the protection of human subjects from research risks, and 2) inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion or exclusion of children, justified in terms of the scientific goals and research strategy proposed?

Environment
Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

Budget and Period of Support
Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research.

Section V. Award Administration Information
Award Notices
A formal notification in the form of a Notice of Grant Award (NGA) will be provided to the applicant for successful applications. The NGA signed by the PI as well as any other applicable individuals is the authorizing document and will be sent via email to the WVCTSI Chief Financial Officer. Awardees must comply with any

funding restrictions described in *Section III*. Selection of an application for award is not an authorization to begin performance. Any costs incurred before receipt of the NGA are at the recipient's risk.

Reporting
PIs that receive a Clinical and Translational Pilot Grants Program award will be required to submit a quarterly report (PGPR), per the established due dates for the quarterly reports. The schedule for the quarterly reports is as follows:

Period of Performance		**PGPR Due Date**
Start of Quarter	**End of Quarter**	
July 1st	September 30th	Due October 15th
October 1st	December 31st	Due January 15th
January 1st	March 31st	Due April 15th
April 1st	June 30th	Due July 15th

A final progress report, invention statement, and the expenditure data portion of the Federal Financial Report are required for closeout of an award, as described in the NIH Grants Policy Statement.

Section VI. Clinical and Translational Pilot Grants Program Contacts
We encourage inquiries concerning this funding opportunity and welcome the opportunity to answer questions from potential applicants.

Assistance	**Contact**	**Phone Number**	**Email**
General Questions	Anne Bolyard	304-581-1963	aebolyard@hsc.wvu.edu
Pilot Grant Submissions and General Questions	Wesley Kimble	304-581-1957	wkimble1@hsc.wvu.edu
General Questions	Meghan Reeves	304-293-6581	mreeves1@hsc.wvu.edu