West Virginia Clinical and Translational Science Institute
Request for Applications

Part 1. Overview Information
Funding Opportunity Purpose
The goal of this Request for Applications (RFA) is to support clinical and translational pilot projects relevant to improving health in West Virginia and Appalachia.

Applicants are encouraged to meet with the Pilot Project Program Coordinators prior to application submission.

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Required Letter of Intent (LOI)
To better serve those applying for West Virginia Clinical and Translational Science Institute pilot project funding, Letters of Intent (LOI) will be required from interested Co-Project Leaders (Co-PLs)/Co-Principal Investigators (Co-PIs). The proposed collaborative projects should address health care needs of West Virginia. Examples include, but are not limited to, the following health care issues:

- Addiction and Resultant Emerging Epidemics (hepatitis C)
- Cancer
- Cardiovascular Disease
- Chronic Lung Disease
- Neuroscience

The LOI should include the following components; guidance on these requirements is located in Section IV. LOI template can be found here. Application and Submission Information:

- Cover Page
- Project Abstract
- Proposed Project Description
  - In one page or less, please describe the rationale and health care issue addressed, proposed project objectives, and potential impact addressed by the proposed study.
- NIH Biographical Sketch of Both Co-PIs
LOI Due Date – March 15th, 2017 by 5:00 PM EST

LOIs are required and must be submitted via email as a single PDF document on or before the deadline. Applications should be emailed to Wes Kimble via email wkimble1@hsc.wvu.edu. The LOIs will be used to facilitate planning for the proper reviewers needed for the evaluation of the full proposals. In addition, the LOIs will be used to provide feedback to further strengthen the full proposal application.

All Co-PIs will receive an e-mail notification after the LOI has been reviewed as well as any additional feedback from the LOI reviewers. Unsolicited full proposals from Co-PIs that do not submit a LOI by the 3/15/17 deadline will not be reviewed nor considered for funding.

Full Proposal Due Date – May 1st, 2017 by 5:00 PM EST

Budget
For all funding cycles, the budget is limited to a maximum of $50,000 in total direct costs for twelve (12) months, with each site submitting similar budget totals. Applicant teams are encouraged to submit proposals with budgets that are approximately equally supported from 2 institutions, however exceptions may be made on a case by case basis.

Compliance Requirements for a Full Proposal
Co-PIs submitting a full proposal in response to this RFA must include CITI certification for investigators conducting research or collecting outcomes with human subjects as well as documentation of IRB protocol submission and/or IACUC protocol submission. Documentation for these requirements should be included in the Appendix of the application. IRB and IACUC approval are not required prior to application submission deadline but must be completed within 30 days of notice of grant award.

Additional Information on Eligibility
- A minimum of two Principal Investigators (PI) are required for this funding opportunity, coming from at least 2 different participating institutions (MU, WVSOM, WVU (including all campuses)).
- One of the two Co-PIs is designated as the lead/contact PI; her or his name should appear on the cover page.
- All Co-PLs/Co-PIs must hold a faculty appointment or equivalent at the time the award is announced. 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.
- All Early Stage Investigator (ESI) PI must complete the one page attachment with signature from proposed mentor. Mentorship Agreement Plan can be found here. Early Stage Investigator(ESI) Principal Investigators, as defined by the NIH as 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.

Those with questions or concerns related to the various requirements may contact Wes Kimble, wkimble1@hsc.wvu.edu

Part 2. Full Text of Announcement

Section I. Funding Opportunity Description
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.
Updated on FEB 1, 2017
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.

Section II. Full Application Guidance
Award Project Period
The scope of the proposed project should determine the project period. The maximum project period is twelve (12) months.

Section III. Eligibility Information
For both the LOI as well as the full proposal, PI eligibility is limited to the following:

- A combination of two of the following institutions MU, WV SOM, and WVU (all campuses) should be represented by one Co-PL/Co-PI each on the proposed research team;
- All Co-PIs must hold a faculty appointment or equivalent at the time the award is announced. 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 West Virginia Health Grant Partnership projects.
- Any Early Stage Investigator (ESI) applicants are required to submit a one page mentoring agreement plan in the proposal appendix.

Additional Information on Eligibility–Number of Applications
Co-PLs/Co-PIs can only submit one LOI under this RFA. Individuals may serve as co-investigators or project team members on more than one proposal. Those with questions or concerns related to the various requirements may contact Wes Kimble at wkimble1@hsc.wvu.edu

Section IV. Application and Submission Information

Format Specifications
Font restrictions: Use a font size of 11-point 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 (9 or 10 point) but it must be in black, readily legible and follow the font typeface requirement. Color can be used in figures; however, all text must be in black, clear and legible.
Page Limits: Although many sections of the 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 the personnel listed in Section VII with any questions prior to the submission of your West Virginia Health Grants Partnership application. Applications must be submitted via email as a single PDF document by the close of business (5:00 pm EST) on or before the deadline date. The application must include the following:

Cover Page: The cover page should include the following items on a single page:

- Title of the Proposed Project
- Health Care Issue Addressed by the Proposed Project
- Contact Information for Co-PIs
- Total Amount of Requested Funding
- Performance Site(s)

Project Abstract: Please summarize the proposed project by describing the following items in no more than one page.

Approach/Research Plan: Please use NIH PHS 398 Continuation Page. This section is limited to 5 pages and should include Specific Aims, Hypothesis, Background, 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—Hypothesis, Background, 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.

(d) 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.

(e) 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.

- **Timeline**: for all human subjects enrollment studies please include a timeline of your recruitment schedule and a short plan to mitigate enrollment delays. Applicants are encouraged to meet with WVCTSI Pilot Project Coordinators so that they may introduce applicants to clinical trials coordinators, as well as informatics and biostatistics experts.

**Human Subjects Protection Section**: please use NIH PHS 398 Continuation Page (NIH Forms) and address all appropriate bulleted items below (no page limit):

- 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
Updated on FEB 1, 2017

**Budget:** For all funding cycles, the budget is limited to a maximum of $50,000 in total direct costs with a performance period of twelve months. Each site is required to 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.
- Salary and fringe support for administrative assistance, students, graduate students, clinical trainees, post-doctoral and clinical fellows are permitted
- Travel funds that are needed for study conduct are allowed, if essential. Travel to collect data or for collaboration purposes can be justified separately in the budget section. Travel expenses not to exceed $2,500 may be budgeted for conference attendance to deliver presentation of study results.
- Equipment essential for the conduct of the study (up to $5,000)
- Publication fees (not to exceed $2,000.00 per application)
- Data analysis costs
- Research assistant salary support; applicants must account for fringe benefit costs when considering research assistant salary levels.
- Non-faculty personnel salary support
- 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
- Rent of offsite facilities

**Unallowable Costs**
- Funds cannot be used to support salary of the Co-PIs or other investigators with faculty appointments. Co-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 as institutional commitment towards the West Virginia Health Grant Partnership 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.

**Budget Justification**

- **Personnel:** If possible, please name Co-Investigators, graduate students, undergraduate students, or postdoctoral associates in your budget justification. Naming an individual in the budget justification does not represent a commitment on your part to hire that individual.
- **Equipment:** Equipment costs (equal to 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.
- **Travel:** Include a list of the names of conferences under consideration for attendance in the budget for each year of the proposal and indicate whether they are domestic or international ($2,500 maximum). For field work and other research-related travel, please provide detailed information about the number of people making each trip, its duration and other information.
- **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.
- **Publication/Documentation/Dissemination Costs:** $2,000 maximum.
- **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/Sub-awards: 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 Contacts) to determine who you should reach if you have any additional questions regarding subcontracts/sub-awards.

Offsite Rental Costs: Provide quotes, location and justification for the rental of offsite rental costs.

Other Direct Costs: Provide quotes, catalog prices or other published information to justify proposed rates for other costs.

Appendix Requirements
- Outline of clinical protocol (if study is an investigator-initiated clinical trial and not described in the proposal).
- A Biosketch in NIH Format (5 page maximum) must be submitted for all key research personnel. Be sure to include the following sections in the Biosketch: Section A - Personal Statement; Section B – Positions held and honors received; Section C – Contributions to Science; and Section D – Research support.
- Documentation on regulatory approvals (CITI training for Protection of Human Subjects, Animal Assurances, etc. if applicable).
- 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 (at least 10% effort during the period of performance) to complete the research will be available.
- Mentorship Agreement Plan: ESI PIs must complete the one page attachment with signature from proposed mentor. Mentorship Agreement Plan can be found here.

Other Submission Requirements and Information
The West Virginia Health Grants Partnership Grant application package must be submitted as a single PDF document via email by 5:00 PM EST by the deadline date to Wes Kimble at wkimble1@hsc.wvu.edu. All Co-PIs will be sent confirmation of her/his application being received via email.

Section V. Application Review Information
Only the review criteria described below will be considered in the review process; the review panel will be comprised of subject matter experts from MU, WVSOM, and WVU as well as any additional subject matter experts from other institutions/organizations. Reviewers will provide an overall impact score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on clinical care or the research field(s) involved with the proposed project.

Scored Review Criteria
Reviewers will consider each of the review criteria below and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have major scientific impact. (E.g., 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?

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,
Updated on FEB 1, 2017

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 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 environment, subject populations, or collaborative arrangements?

**Additional Review Criteria**

As applicable for the project proposed, reviewers will evaluate the following additional items while determining scientific and technical merit. They will provide an overall impact score but will not give separate scores for these items.

**Assurances for Human Subjects**

For research that involves human subjects but does not involve one of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their participation according to the following five review criteria: 1) risk to subjects, 2) adequacy of protection against risks, 3) potential benefits to the subjects and others, 4) importance of the knowledge to be gained, and 5) data and safety monitoring for clinical trials. For research that involves human subjects and meets the criteria for one or more of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate: 1) the justification for the exemption, 2) human subjects involvement and characteristics, and 3) sources of materials. For additional information on review of the Human Subjects section, please refer to the Guidelines for the Review of Human Subjects.

**Vertebrate Animals**

The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following five points: 1) proposed use of the animals, and species, strains, ages, sex and numbers to be used; 2) justifications for the use of animals and for the appropriateness of the species and numbers proposed; 3) adequacy of veterinary care; 4) procedures for limiting discomfort, distress, pain and injury to that which is unavoidable in the conduct of scientifically sound research including the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices; and 5) methods of euthanasia and reason for selection if not consistent with the AVMA Guidelines on Euthanasia. For additional information on review of the Vertebrate Animals section, please refer to the Worksheet for Review of the Vertebrate Animal Section.

**Biohazards/Biosafety**

Reviewers will assess whether materials or procedures proposed are potentially hazardous to research personnel and/or the environment and, if needed, determine whether adequate protection is proposed.

**Radiation Safety and Hazardous Materials**
Updated on FEB 1, 2017
Projects involving the use of radioactive material must be reviewed and approved by the Radiological Safety Committee before any materials can be ordered and work begun at any institution. Any questions pertaining to WVU policy and procedures can be answered by referring to: http://www.hsc.wvu.edu/rsafety/. For questions pertaining to MU policies, please contact Dr. William McCumbee at mccumbee@marshall.edu.

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.

Review and Selection Process
As part of the scientific peer review, all applications:

- Will be assessed on the scientific and technical merit of the proposed project and relevance of the proposed project to outlined programmatic priorities
- May undergo a selection process in which only those applications deemed to have the highest scientific and technical merit (generally the top half of applications under review) will be discussed and assigned an overall impact score.
- Will receive a written critique.

Final funding decisions will be made by WVCTSI leadership (with NIH and external advisory committee approval), taking into consideration programmatic priorities and availability of funds. Appeals of initial peer review will not be accepted for applications submitted in response to this RFA.

Funding Priorities: 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.
- Thematic focus topics related to cancer, neuroscience, addiction and related emerging epidemics, 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. 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.
Section VI. 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 designated authorized Financial Officer of WVU as well as MU. 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
Co-PIs that receive a WVCTSI Pilot Award will be required to submit a progress report every three (3) months as defined by the project period of performance. A final progress report, invention statement and the final itemized expenditures are required for closeout of an award.

Section VII. Contacts
We encourage inquiries concerning this funding opportunity and welcome the opportunity to answer questions from potential applicants.

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<th>Contact</th>
<th>Institution</th>
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<th>Email</th>
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<tr>
<td>Wes Kimble</td>
<td>WVU (and general inquiries)</td>
<td>304-581-1957</td>
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